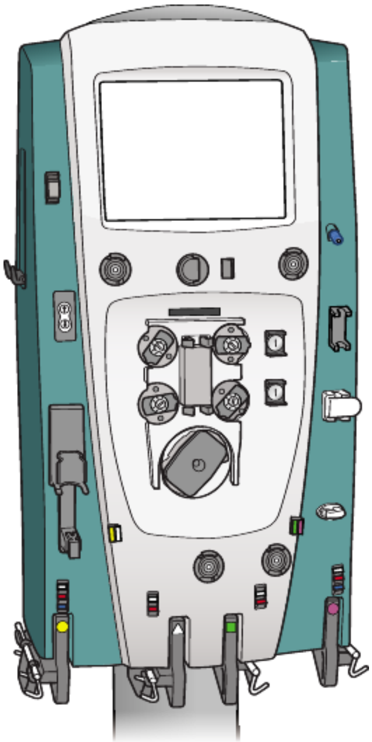
Prismaflex®



Service Manual

For use with software version 7.xx

Manufacturer:

Gambro Lundia AB
Box 10101, Magistratsvägen 16, SE-220 10 Lund, Sweden
Tel: +46-46-16 90 00, Fax: +46-46-16 96 96
www.gambro.com

Questions or comments about this publication can be directed to your local representative or to the manufacturer.

Order number:

G5005209

Copyright:

This page is intentionally left blank

Prismaflex® Service Manual

1. Before you get started
2. Installation Guide
3. Technical Description
4. Function Check
5. Alarms and Troubleshooting
6. Maintenance
7. Schematics
8. Specifications
9. Equations

Contents

1. Before you get started

About this Manual . . . 1:2
Keywords Used in this Manual . . . 1:2
Complaint . . . 1:3
Responsibility and Disclaimer . . . 1:3
Safety Definitions . . . 1:4
Maintenance . . . 1:5
Competence of Service Engineers . . . 1:5
Technical Support . . . 1:5
Symbols . . . 1:6
Electrical Safety . . . 1:6
Instructions and warnings . . . 1:6
Information . . . 1:7
Communication . . . 1:8
Environmental . . . 1:8
Transportation and storage . . . 1:8
Solutions . . . 1:9
Certification Marks . . . 1:10
Disposal . . . 1:10
Disposal of Discarded Equipment . . . 1:10

2. Installation Guide

About this Chapter . . . 2:2
Installation . . . 2:3
Contents of Prismaflex® Control Unit Shipping Carton . . . 2:3
Electrical Requirements . . . 2:4
Electromagnetic Environment Requirements . . . 2:4
Space Requirements . . . 2:4
Unpacking and Assembly . . . 2:4
Unpacking . . . 2:4
Connect Power Cord . . . 2:5
Install Scale Carrying Bars . . . 2:6
Attachment of caution label . . . 2:6
Change of Syringe Clip . . . 2:7
Prismaflex® Control Unit Calibrations . . . 2:7
Electrical Safety Inspection . . . 2:8
Installation Test . . . 2:8
SW update . . . 2:11
Calibrate the display . . . 2:12

3. Technical Description

Prismaflex® Control Unit . . . 3:2
Prismaflex® Control Unit Functions . . . 3:2
Prismaflex® Control Unit Components . . . 3:3
Front Panel Components . . . 3:3
Rear Panel Components . . . 3:14
Interior Components . . . 3:16
Interior — Door (Closed hatch) . . . 3:16
Interior — Door (Opened hatch) . . . 3:16

Interior — Front 1 . . . . 3:18
Interior — Front 2 . . . . 3:20
Interior — Front 3 . . . . 3:22
Interior — Front 4 . . . . 3:24
Electrical Description 3:28
Internal Connections 3:28
Modules 3:31
Power Supply 3:33
Carrier Board 3:34
Control CPU 3:35
Protective CPU board 3:36
ARPS board 3:38
PIB board 3:40
Alarm light module 3:41
LVDS interface board 3:41
External RS232 board 3:41
External Ethernet board 3:41
External Remote Alarm Connector 3:42
Fluid pumps 3:42
Blood pump 3:42
Syringe pump 3:43
Loader 3:43
Scales 3:43
ABD assembly 3:44
Signals 3:45

4. Function Check

About this Chapter 4:2
Main-controlled Components 4:3
Self–tests 4:4
Operating System Initialization 4:4
Initialization Test 4:5
Prime Self-test 4:8
Pre-Prime 4:8
Post-Prime 4:13
Periodic Self-test 4:21
Alarm Monitoring During the Periodic Self-Test 4:23
Technical Screens 4:24
First Technical Screen 4:24
Second Technical Screen 4:29
Third Technical Screen 4:32
Fourth Technical Screen 4:35
Fifth Technical Screen 4:36
Sixth Technical Screen 4:37

5. Alarms and Troubleshooting

About this chapter 5:2
Warning Alarms 5:3
Prismaflex® Control Unit Actions 5:3
Operator Response 5:3
Overridden Warning Alarms 5:4
Malfunction Alarms 5:5

Prismaflex® Control Unit Actions 5:5
Operator Response 5:5
Overridden Malfunction Alarms 5:6
Caution Alarms 5:7
Prismaflex® Control Unit Actions 5:7
Operator Response 5:7
Advisory Alarms 5:8
Prismaflex® Control Unit Actions 5:8
Operator Response 5:8
Overridden Advisory Alarms 5:8
Alarm Priorities 5:9
Alarm Priority List 5:9
Troubleshooting 5:14
About the Troubleshooting Chapter 5:14
Warning Alarms 5:15
Caution Alarms 5:39
Advisory Alarms 5:48
Malfunction Alarms 5:66
Miscellaneous 5:97
Power Failure 5:101

6. Maintenance

About this Chapter 6:3
Electrical Safety Inspection 6:4
General 6:4
Visual inspection 6:5
PET - Protective Earth Test 6:5
Note: 6:5
Test equipment 6:5
Test 6:5
Check of Conductivity Clip 6:6
Test equipment 6:6
Test 6:6
ELT / PLT 6:6
Test equipment 6:6
General conditions for ELT / PLT 6:6
ELT - Earth Leakage Current Test 6:6
PLT - Patient Leakage Current Test 6:7
Test 6:8
Record of Electrical Safety Inspection 6:9
Visual inspection 6:9
Remarks: 6:9
Conductivity Clip Test 6:9
PET - Protective Earth Test 6:9
ELT - Earth Lekage Current Test 6:10
PLT-Patient Leakage Current Test 6:10
Component replacement with needed ESI 6:12
Preventive Maintenance 6:13
Tools Needed 6:13
Working Time 6:14
Prismaflex® PM Kit 6:14
Visual Inspection and Cleaning 6:15
Component Replacement 6:17

Power Supply Check 6:20
Exchange of Lead Batteries for Battery Backup 6:20
Service Mode - Checkout using Service Diagnose Mode 6:21
Service Screens 6:22
Service - Diagnose Screens 6:24
Diagnose Screen – Pumps Diagnose 6:26
Diagnose Screen – Scale Diagnose 6:28
Diagnose Screen – Pressure Pod Reposition 6:30
Diagnose Screen – Alarms Tone and Light 6:32
Diagnose Screen – Air Detector 6:34
Diagnose Screen – Syringe Pump 6:36
Diagnose Screen – Clamp and Pinch Valves 6:41
Diagnose Screen – BLD (Blood Leak Detector) 6:43
Diagnose Screen – Internal 6:44
Diagnose Screen – Communication 6:45
Diagnose Screen – PM timer and Date 6:53
Diagnose Screen – Clean Screen 6:55
Diagnose Screen – SW Configuration 6:56
Diagnose Screen – 2D Barcode 6:57
Service Calibration Screens 6:58
Calibration Screen – Language Configuration 6:60
Calibration Screen – Scales Calibration 6:61
Calibration Screen – Pressure Sensors Calibration 6:64
Calibration Screen – Syringe Pump Calibration 6:66
Calibration Screen – Filter Clotting Limits 6:68
Calibration Screen – Set Clock and Date 6:69
Calibration Screen – Screen Brightness Calibration 6:70
Calibration Screen – Pitch and Volume 6:71
Calibration Screen – External Communication Interface 6:72
Calibration Screen – Therapy/Sets Configuration 6:73
Calibration Screen – Anticoagulation Configuration 6:76
Calibration Screen – Anticoagulation Solutions 6:78
Calibration Screen – Serial Number 6:84
Calibration Screen – Air Detector 6:85
Calibration Screen – IP Settings 6:86
Calibration Screen – Syringe Holder Configuration 6:87
Calibration Screen – Supplementary Syringe 6:88
Calibration Screen – Settings Handling 6:90
Calibration Screen – Blood Warmer Configuration 6:92
Functional Test 6:94
Final Check 6:97

7. Schematics

8. Specifications

Performance 8:3
Flow Rates and Accuracy 8:3
Blood Flow Rate 8:3
Automatic Blood Return Volume 8:3
Replacement Solution/Fluid Flow Rate 8:3
Dialysate Flow Rate 8:3
PBP Solution Rate 8:4
Patient Fluid Removal Performance / Patient Plasma Loss Performance 8:4

Effluent Flow Rate . . . 8:4
Syringe Settings . . . 8:5
Systemic, Prismaflex syringe pump anticoagulation method . . . 8:5
Citrate – Calcium, Prismaflex Syringe Pump anticoagulation method . . . 8:6
TPE Settings . . . 8:6
Pressure sensor range, accuracy and alarm limits . . . 8:6
Access . . . 8:6
Return . . . 8:7
Filter . . . 8:7
Effluent . . . 8:9
Patient safety . . . 8:9
Air Bubble Detector . . . 8:9
Blood Leak Detector . . . 8:9
Alarm signals . . . 8:10
Audible . . . 8:10
Sound pressure levels . . . 8:10
Characteristics . . . 8:10
Visual . . . 8:10
Physical Data . . . 8:11
Weight, dimensions, etc. . . . 8:11
Scales Characteristics . . . 8:11
Scale Weight Range . . . 8:11
Scale accuracy: . . . 8:11
Power . . . 8:11
Line power . . . 8:11
Battery backup . . . 8:12
External communication . . . 8:12
Environmental data . . . 8:13
Operation . . . 8:13
Transportation and Storage . . . 8:13
Noise level . . . 8:13
Vibration levels . . . 8:14
Fluid spillage . . . 8:14
Cleanability . . . 8:14
Electromagnetic Emissions and Immunity . . . 8:14
Electrical Safety . . . 8:19
AC Leakage Current . . . 8:19
Defibrillation-proof Applied Part . . . 8:19
Radio Frequency Interference . . . 8:19
Electromagnetic Compatibility . . . 8:19
Potential Equalization . . . 8:20
Continuous Operation . . . 8:20
Conformity to International Rules . . . 8:21
Medical Device Classification . . . 8:22
Prismaflex® Disposable Sets . . . 8:23
CRRT Disposable Sets . . . 8:24
Low flow sets . . . 8:24
Priming parameters and Blood flow rates . . . 8:24
Patient fluid removal and Patient fluid loss/gain limit . . . 8:24
Solution flow rates . . . 8:25
Return Blood and Recirculation flow rates . . . 8:25
High flow sets . . . 8:26
Priming parameters and Blood flow rates . . . 8:26
Patient fluid removal and Patient fluid loss/gain limit . . . 8:26

Solution flow rates 8:27
Return Blood and Recirculation flow rates 8:27
TPE Disposable Sets 8:28
Low flow sets 8:28
Priming parameters and Blood flow rates 8:28
Return Blood and Recirculation flow rates 8:28
High flow sets 8:29
Priming parameters and Blood flow rates 8:29
Return Blood and Recirculation flow rates 8:29
HP Kits 8:30
Priming parameters and Blood flow rates 8:30
Return Blood and Recirculation flow rates 8:30

9. Equations

Blood pump flow rate 9:2
Filter pressure drop 9:2
Effluent flow rate 9:2
Transmembrane pressure 9:3
Total predilution 9:3
CRRT prescription indicators 9:3
Filtration Fraction 9:3
Doses 9:4
Patient fluid removed 9:5
Access transmembrane pressure 9:5
Software Calculations of Target Patient Plasma Loss 9:5
Formulas used in TPE 9:6
Patient plasma loss 9:6
PBP flow rate 9:7
Syringe flow rate 9:7

This page is intentionally left blank

Chapter 1

Before you get started

About this Manual 1:2
Keywords Used in this Manual 1:2
Complaint 1:3
Responsibility and Disclaimer 1:3
Safety Definitions 1:4
Maintenance 1:5
Competence of Service Engineers 1:5
Technical Support 1:5
Symbols 1:6
    Electrical Safety 1:6
    Instructions and warnings 1:6
    Information 1:7
    Communication 1:8
    Environmental 1:8
    Transportation and storage 1:8
    Solutions 1:9
    Certification Marks 1:10
Disposal 1:10
    Disposal of Discarded Equipment 1:10

About this Manual

This service manual provides the information needed to install the Prismaflex control unit, to carry out maintenance, component replacements and calibrations. It is a guidance on how to identify and repair faults that may occur.

All available spare parts to be used for the Prismaflex control unit are found in the illustrated Spare Parts List.

This service manual also provides a technical description of the functionality of the Prismaflex control unit, including technical data.

Keywords Used in this Manual

Authorized service technicians
This term refers to Gambro trained and certified service technicians.

Filter
Depending on the therapy in use, Filter stands for either:

- Hemofilter/Dialyzer
- Plasmafilter
- Hemopurification cartridge

Manual
The term Manual refers to this Service Manual unless specified differently.

Operator
In this manual, Operator designates appropriately trained and qualified clinical staff who is in charge of the Prismaflex control unit. The operator sets the prescribed values in accordance with the prescribed treatment, responds to alarms, troubleshoots the Prismaflex control unit, handles the bags, etc. Once the training material is read through and understood, the operator is approved to operate the Prismaflex control unit. The operator works within one meter from the front of the Prismaflex control unit.

Responsible Organization
In this manual, Responsible Organization means a function or a person who can identify, analyze, and control potential risks that could occur, for example, when connecting the Prismaflex control unit to other equipment or when making changes to the equipment connected to the Prismaflex control unit.

Screens
The Prismaflex control unit displays different screens during operation. Whenever a screen is referred to in this manual, it is identified by its title, e.g. `Enter Flow Settings` screen or `Status` screen.

Softkeys
Whenever a Softkey on the Prismaflex screen is referred to in this manual, it is written in capital italic letters, e.g. *NEW PATIENT* or *CHANGE BAG*.

Training Material
The operator's manual is the primary training material for staff who is to operate the Prismaflex system. See section “Competence of Service Engineers” on page 1:5, for information concerning the minimum level of competence required for service engineers.

Complaint

If a complaint is raised it shall be communicated to the relevant Gambro Sales Company. In order for the Sales Company to be able to determine the relevance of a complaint, it is of vital importance that the deviation is communicated to them as comprehensive as the issue requires.

Responsibility and Disclaimer

Gambro accepts responsibility for the safety, reliability, and performance of this equipment only:

- If any modifications to the equipment have been authorized in writing by Gambro and carried out by an authorized service technician.
- If the electrical installation for powering the equipment complies with all applicable local electrical codes and requirements including, if applicable, IEC requirements.
- If the equipment is used in accordance with the Service Manual and the Operator's Manual.

Gambro will provide, on request, a service manual which contains all necessary circuit diagrams, calibration instructions, and service information to enable authorized service technicians to repair those parts of this equipment which Gambro considers to be repairable.

Gambro does not accept any responsibility or liability for use of accessories or disposables other than those specified in this manual or if any specified accessory or disposable is not used in accordance with this manual, online instructions and the *Instructions for Use* accompanying those accessories and disposables.

Since Gambro has no control over service work which is not performed by authorized service technicians, Gambro will in no way be responsible or liable for any damages resulting from the operation or performance of any device, or any injury caused thereby, after repair has been performed by any person other than an authorized service technician of Gambro.

Under no circumstances will Gambro be liable for any indirect, incidental, special or consequential damages of any kind, its liability being hereby limited solely to repair or replacement.

Safety Definitions

This manual uses the following safety definitions :

WARNING

⚠ A warning alerts the reader about a situation which, if not avoided, could result in an adverse reaction, injury or death.

WARNING

CAUTION

! A caution alerts the reader about a situation which, if not avoided, could result in minor or moderate injury to the user or patient or damage to the equipment or other property.

CAUTION

Note: Notes are added to give more information.

Maintenance

To ensure proper operation of the Prismaflex control unit, an authorized service technician must perform a complete series of maintenance procedures at regular intervals.

The maintenance and calibration information is provided in this Service Manual, see Preventive Maintenance on page 6:13.

It is mandatory to perform at least one preventive maintenance once a year or every 6000 hour. The rate of preventive maintenance might be different due to variations of the operating environment.

Competence of Service Engineers

There is a certain minimum level of competence required for Service Engineers who maintain and repair Gambro products, summarized as follows.

A Service Engineer is considered authorized if he/she has:

1. Attended Prismaflex technical service course and has been given a certificate stating that the technician has passed the course.

2. Access to the recommended test equipment and special tools detailed in this Service Manual.

3. Access to the recommended Prismaflex control unit - Spare parts List.

4. Access to and understanding of the Prismaflex control unit - Service manual and the Prismaflex control unit - Operator's Manual.

In general, this policy implies that training will be carried out by Gambro Lundia AB, while local markets are responsible for their own service organization.

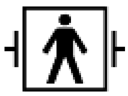
Technical Support

For technical support please contact your local Gambro Service representative or visit the website.

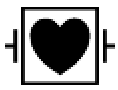
Symbols

If applicable, the following symbols appear on or near the serial number label or other permanently affixed labels of this device. For more information, see chapter 8: “Specifications” on page 8:2.

Electrical Safety



Equipment applied part is Type BF, defibrillation - proof per IEC 60601-1.
Note: To be sure of the Prismaflex control unit’s classification see type label found at the back of the Prismaflex control unit.

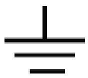


Equipment applied part is Type CF, defibrillation-proof per IEC 60601-1.
Note: To be sure of the Prismaflex control unit’s classification see type label found at the back of the Prismaflex control unit.

IPX1 Device meets the “drip proof” classification requirements.

Device requires an alternating supply current.

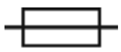
Nearby high-voltage conductors could be hazardous if contacted.



This symbol is located near functional ground locations on this device.

This symbol is located near protective ground locations on this device.

This symbol identifies the point of connection of a potential equalization conductor.
The terminal is connected to the chassis and should be connected to corresponding terminals on other equipment in order to eliminate potential differences.



Fuse.

Certain components within this equipment are sensitive to electrostatic discharge.

Instructions and warnings

Attention, consult accompanying documents.

Read instructions before use.

This symbol warns against an incline of the Prismaflex control unit of more than 5° from the floor.
Note: This warning label must be applied on the warmer holder before use. It should be mounted on deliverance. The background color is yellow.

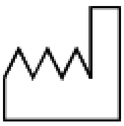
Pull out scale completely before hanging bag.

Pull out scale completely before hanging bag.

Risk of tipping the Prismaflex control unit from pushing, leaning, resting, etc. The colors are red, white, and black.

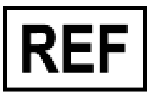
This symbol is applied on the stand if the Prismaflex calibration weight kit is stored inside. Calibration weights are to be removed before tilting the Prismaflex control unit into horizontal position.
The color is black on a yellow background.

Information

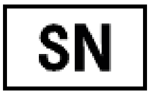


Date of manufacture with year as four digits.

Manufacturer. The year of manufacture may be included in the symbol expressed as four digits.

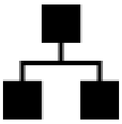


Catalog number.



Serial number.

Communication

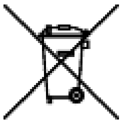


Ethernet port.

RS232 Serial Communication port.

Remote alarm connection.

Environmental

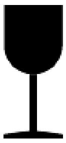


This symbol indicates that:
– since the equipment contains dangerous substances, it must be recycled rather than disposed together with other municipal waste;
– the equipment was placed on the market after 13 August 2005.

The device contains toxic or hazardous substances or elements.

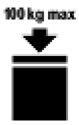
Recycle the cardboard.

Transportation and storage



Fragile – handle with care.

Keep dry.

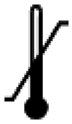


The maximum stacking load permitted on the transport package is 100 kg.

This end up.

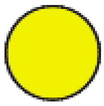
Atmospheric pressure limitation. Upper and lower limits are expressed with numeric values in kPa.

Humidity limitation. Upper and lower limits are expressed with numeric values in %.

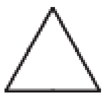


Temperature limitation. Upper and lower limits are expressed with numeric values in degrees Celsius or Fahrenheit.

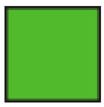
Solutions



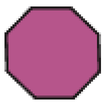
Circle sign; placed as colored symbol on effluent scale and in the graphical user interface in screens related to effluent. On the disposable set the symbol is a relief shape in the plastic cover indicating the effluent pump.



Triangle sign; placed as colored symbol on PBP scale and in the graphical user interface in screens related to PBP. On the disposable set the symbol is a relief shape in the plastic cover indicating the PBP pump.



Square sign; placed as colored symbol on dialysate scale and in the graphical user interface in screens related to dialysate. On the disposable set the symbol is a relief shape in the plastic cover indicating the dialysate pump.



Octagon sign; placed as colored symbol on replacement scale and in the graphical user interface in screens related to replacement. On the disposable set the symbol is a relief shape in the plastic cover indicating the replacement pump.

Certification Marks

The CE-conformity mark indicates that the Prismaflex control unit conforms to the requirements in the EC Council Directive 93/42/EEC of 14 June, 1993 concerning medical devices. It also indicates that the notified body British Standards Institution (BSI, No. 0086) has approved the Quality Management System. The CE conformity mark is only valid for the Prismaflex control unit. Disposables and any accessories specified for use with the Prismaflex control unit are marked with CE conformity marks in their own right.

The CSA (C-US) mark indicates that the Prismaflex control unit conforms to the requirements related to safety of medical devices for the US and Canada. The “C” and the “US” adjacent to the CSA mark indicate that the Prismaflex control unit has been evaluated to the applicable ANSI/UL and CSA standards for use in the US and Canada.

The CCC mark indicates that the Prismaflex control unit conforms to the safety requirements for China Compulsory Certification (CCC) as described by the competent authority Certification and Accreditation Administration of People's Republic of China (CNCA). The “S” adjacent to the CCC mark indicates that safety requirements are met.

Disposal

The Prismaflex control unit shipping carton, foam packing, and other packaging material should be disposed of according to local regulations.

For the purpose of protecting the environment the Prismaflex control unit must not be disposed with general domestic waste, but shall be separately collected for dismantling and recovery. Where applicable national regulations shall be applied. Consult your relevant Gambro Sales Company for information.

Disposal of Discarded Equipment

Discarded electromedical equipment must not be disposed together with municipal waste but must be collected separately in order to guarantee ecologically correct disposal to prevent dispersion of potential pollutants into the environment.

Pay attention to the fact that some components of the Prismaflex control unit (display, batteries, circuit boards, etc.) may contain toxic substances which, if released into the environment, pose a risk to the health of living organisms and the environment itself.

The Prismaflex control unit contains a lithium energy cell and a lead-acid battery. The lithium energy cell is embedded in a semiconductor on the monitor circuit card assembly. When replacing these components, follow local regulations for proper disposal.

Chapter 2

Installation Guide

Contents

About this Chapter 2:2
Installation 2:3
Contents of Prismaflex® Control Unit Shipping Carton 2:3
Electrical Requirements 2:4
Electromagnetic Environment Requirements 2:4
Space Requirements 2:4
Unpacking and Assembly 2:4
Unpacking 2:4
Connect Power Cord 2:5
Install Scale Carrying Bars 2:6
Attachment of caution label 2:6
Change of Syringe Clip 2:7
Prismaflex® Control Unit Calibrations 2:7
Electrical Safety Inspection 2:8
Installation Test 2:8
SW update 2:11
Calibrate the display 2:12

About this Chapter

This chapter describes the installation procedure of the Prismaflex control unit. The installation must be performed by an authorized service technician.

Installation

WARNING

⚠ Read these installation instructions before starting installation. Read the Prismaflex Service Manual and perform the installation test before first use.

⚠ All electrical installations must comply with all applicable local electrical codes and manufacturer specifications.

⚠ The assembled Prismaflex control unit weighs approximately 78 kg (172 lb). Use at least two people to lift it out of the shipping carton. Handle the Prismaflex control unit carefully.

WARNING

Contents of Prismaflex® Control Unit Shipping Carton

Each Prismaflex control unit is pre-attached to a column and a base with casters. The Prismaflex control unit comes packaged with the following items:

- Installation kit:
  - United States-style power cord, with retaining bracket
  - Continental European-style power cord, with retaining bracket
  - 4 screws
  - 4 scale carrying bars
- 20 ml syringe clip
- Pump crank
- Caution stickers
- Potential equalization connector
- Prismaflex Operator's manual on CD

Electrical Requirements

The Prismaflex control unit operates from an electrical power source that delivers the following:

- from 100 (–10%) Vac to 240 (+10%) Vac; from 45 Hz to 65 Hz

It is essential that the power socket is properly grounded and in good condition. If there is any doubt regarding the condition of the power cord, have the wiring checked by a qualified electrician.

Electromagnetic Environment Requirements

The Prismaflex control unit requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Operator's Manual.

Space Requirements

The assembled Prismaflex control unit requires a minimum of 63 cm × 63 cm (25 in × 25 in) of floor space. There must be enough space around the Prismaflex control unit so that all fluid bags can hang freely from the scale carrying bars.

Unpacking and Assembly

CAUTION

! Be careful when you move the Prismaflex control unit, so that you don't make it fall over.

CAUTION

Unpacking

1. Open the shipping carton. Carefully lift the Prismaflex control unit out of the carton and place it upright. Carefully remove the foam packing and pay attention not to damaging the Prismaflex control unit components. Dispose of the shipping carton, foam packing, and other packaging material according to local regulations.

2. Inspect all components, paying particular attention to the front panel of the Prismaflex control unit. If any damage has occurred, immediately contact your local sales or service representative.

Connect Power Cord

Tool needed: Torx T-20

1. Select the appropriate power cord and cable support package.

Note: If the supplied power cord does not fit the wall socket, contact an authorized electrician that can connect the power cord to the wall socket.

2. Insert the power cord into the cable support, so that the cable support fits tightly against the female connector of the power cord. (A)

3. Turn the cable support by half a turn so that the cable support guide is downward. (B)

4. Plug the power cord into the power cord socket on the rear panel of the Prismaflex control unit.

5. Using the 4 screws provided, secure the cable support to the studs on either side of the power cord socket. Tighten the screws using the Torx T-20. (C)

6. The Prismaflex control unit has a connection on the rear panel for a Potential Equalization Conductor. If required, connect the Potential Equalization Conductor to the connector.

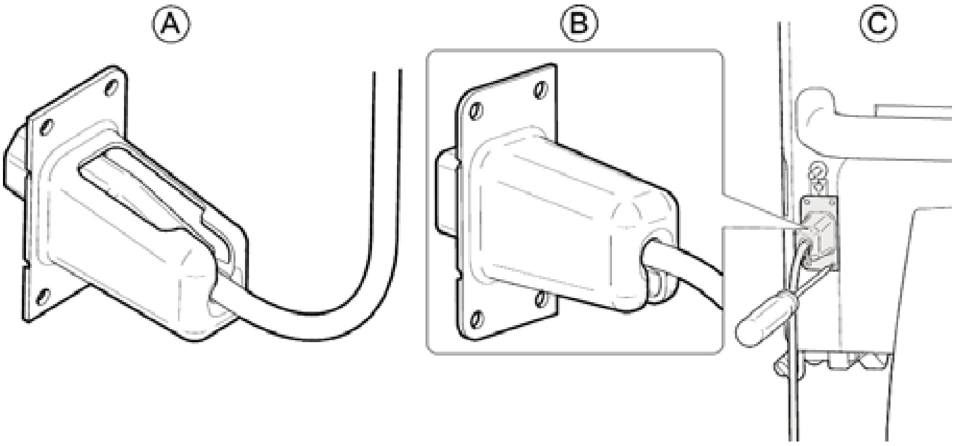


Figure 2:1 Connecting the Power Cord

Install Scale Carrying Bars

Working one scale at a time, install the carrying bars into the bar trays of the four scales.

1. Open the scale, place a carrying bar on the bar tray.

2. Rotate the carrying bar so that the handle is pointing toward the floor; close the scale.

Note: Scale will not close properly unless the handle of the carrying bar is rotated toward the floor.

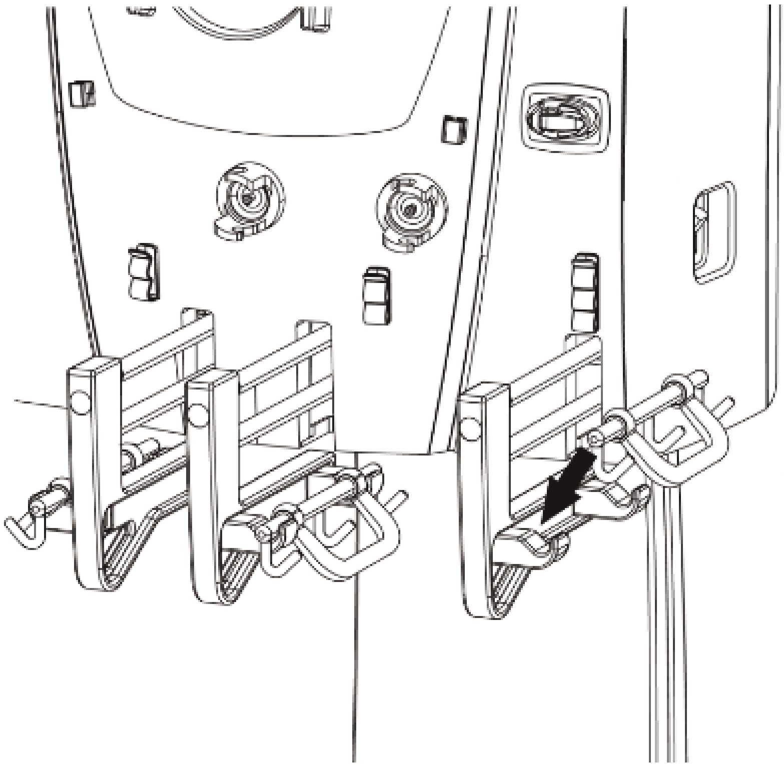


Figure 2:2 Placing the Carrying Bars on the Scales

Attachment of caution label

Tools needed: Cleaning Material

Perform the following steps to attach the caution labels to the front panel:

1. Clean the area of Prismaflex control unit where the stickers are to be placed according to point 3 in Visual Inspection and Cleaning on page 6:15.

2. Place the sticker next to the handle of the Effluent scale and the Replacement scale.

Note: The pictures on the stickers are not identical. Blue area on sticker is to be facing towards the Effluent scale and the Replacement scale.

3. Check that all stickers are firmly attached to the surface of the Prismaflex control unit.

4. Clean the surface on and around the stickers.

Change of Syringe Clip

Tools needed: Torx T-20

Perform the following steps to perform the change of the syringe clip:

1. Enter Service mode, Diagnose Screen - Syringe pump.

2. Using the syringe pump hard keys, move the plunger to its bottom position.

3. Switch off the Prismaflex control unit.

4. Remove the Torx screw (T-20).

5. Slide the syringe plate down.

6. Slide in the new syringe plate.

7. Fasten the screw that holds the syringe plate.

8. Select the correct size of the syringe clip and perform a configuration of the syringe holder, see Calibration Screen – Syringe Holder Configuration on page 6:87.

Prismaflex® Control Unit Calibrations

CAUTION

! The installer is required to use an ESD (electro-static discharge) Grounding Wrist strap during this procedure to avoid unintentional damage to the electronic devices in the Prismaflex control unit.

! Do not remove any cards or IC chips from their antistatic containers until you are ready to install them. When removing cards or chips from a system, immediately place them in an antistatic bag or container.

! When handling cards or IC's, hold them by their edges. Avoid touching the components and connector leads on the card. Avoid touching the leads on the IC.

! Do not slide cards or IC's over any surface. Avoid plastic, vinyl and Styrofoam in your work area.

CAUTION

Before first use of the Prismaflex control unit, the operations below must be performed in Service mode by an authorized service technician and recorded in the Maintenance Log (attached to the inside wall of the rear panel).

Calibration instructions are provided in Service Calibration Screens on page 6:58.

1. Plug the power cord into the wall socket and turn on the Prismaflex control unit.

2. Verify all scales, calibrate if necessary.

3. Verify the syringe pump, calibrate if necessary.

4. Check all pressure sensors, calibrate if necessary.

5. Set the time and date.

6. In service mode, select *CALIBRATE – LANGUAGE CONFIGURATION* and install the required language.

7. Configure therapies, disposable sets, anticoagulation options, and blood warmer, if applicable.

As default the Prismaflex control unit is enabled for CRRT. Default filter set available is M60 and M100.

Electrical Safety Inspection

To ensure proper operation, an Electrical Safety Inspection (ESI) of the Prismaflex control unit shall be performed. Inspection is performed according to instructions found in section “Electrical Safety Inspection” on page “6:4”. Test shall be documented in specific record and stored for future reference.

Installation Test

Note: Read the Service’s Manual before performing the installation test.

Before the first use of the Prismaflex control unit on a patient, the installation test must be performed with a Prismaflex CRRT set in place on the Prismaflex control unit. The installation test verifies that the Prismaflex control unit is properly installed. The test is performed using saline solution as a substitute for priming solution and fluid bags, and a container of water as a substitute for the patient. Successful completion of the installation test indicates that the Prismaflex control unit is functioning properly.

Supplies needed:

- Prismaflex CRRT set
- 4 fluid bags (saline solution) 1000 ml each
- 1 fluid container 1000 ml, filled with 500 ml tap water
- Catheter, 8F

To perform the installation test, follow the steps below;

1. Turn on the Prismaflex control unit. The Prismaflex control unit performs an initialization test to check the system electronics, startup signal sounds twice and status lights (green, red and yellow) are lit during the test.

2. Choose *NEW PATIENT* when the `Choose Patient` screen appears and enter patient information.

3. Check that the *SCUF, CVVH, CVVHD, CVVHDF* softkeys are available on the `Choose Therapy` screen. Choose the *CVVHDF* therapy.

4. Choose *NO ANTICOAGULATION* as `Anticoagulation Method`.

5. Follow the instructions on the screen to load and prime the set. Use saline solution as a substitute to priming and dialysate solutions. The Prismaflex control unit performs multiple self-tests during the priming cycle.

6. When the prime and the prime test are completed, press *CONTINUE*. The `Enter Treatment Settings` screen appears. Set the Loss/Gain Limit to 140 ml/3h. Press *CONFIRM ALL*.

7. The `Enter Flow Settings` screen appears. Set the following flow rates and press the *CONFIRM ALL* softkey.

Blood: 180 ml/min	PBP: 1100 ml/h	Dialysate: 1200 ml/h	Replacement: 1300 ml/h	Fluid Removal Rate: 200 ml/h

8. When the `Review Prescription` screen appears, verify the above flow rates, then press *CONTINUE*.

9. When the `Connect Patient` screen appears, place the access and return lines preferably connected through an 8F catheter into the container of water. Press *CONTINUE*.

10. The `Verify Patient Connection` screen appears. Press the *START* softkey, to enter Run mode.

Note: Because the installation test is performed with water, the `Warning: Return Disconnection` and `Advisory: Cannot Detect Return` alarms could occur after the Prismaflex control unit has entered Run mode. If either of these alarms occur, press *CONTINUE*/*OVERRIDE* (depending on active alarm) and continue with the test. The alarms will not affect the outcome of the installation test.

11. Note the hour and minute on the `Status` screen when the Prismaflex control unit enters Run mode (this information can be found in `History` screen, pressing *EVENTS* softkey).

12. Run the installation test for at least 15 minutes.

13. Place a clamp on the access line (red) below the cartridge. The `Warning: Access Pressure Extremely Negative` alarm should occur. Verify that the red light is flashing and the audible alarm sounds with a high sound, 10 sound pulses repeated approx. every 8 seconds.

14. Unclamp the access line and press the *CONTINUE* softkey on the `Warning` screen. Verify that the alarm is cleared (`Warning` screen leaves display, green light lit).

15. Check the Battery Backup function.
    Note: Performed only if the Prismaflex control unit has Battery Backup installed. See section "Third Technical Screen" on page 4:32, Power section. Otherwise continue with step 19.
    Disconnect the power cord from the wall socket. The `Advisory: Main Power Lost` alarm should occur. Verify that the yellow light is permanently lit and the audible alarm sounds with a low sound, 2 sound pulses repeated approx. every 21 seconds.

16. Press the *OVERRIDE* softkey. The `Advisory` screen leaves the display, but remains in Examine Alarms. Yellow light is lit, the Prismaflex control unit returns to the Status screen and the battery icon, in the top right corner of the display, is lit.

17. Connect the power cord to the wall socket. Verify that the battery icon disappears and that the Prismaflex control unit continues in run mode. Verify that the alarm is cleared from the Examine Alarms (press *SYSTEM TOOLS* softkey and verify that the *EXAMINE ALARMS* softkey is not present) and green light lit.

18. Press the *STOP* softkey, then press the *END TREATMENT* softkey and follow the instructions to unload the set.

19. In service mode, select *Diagnose Screen – PM timer and Date*. Set and verify the PM timer.

20. Document the Prismaflex control unit configuration with either of the following:

    - Download the logging data of the simulated treatment (LOX file) from the technical data card, and attach it to the GFS record, OR

    - Download the logging data of the simulated treatment (LOX file) from the technical data card, and email it to barcode@gambro.com, OR

    - Take a photo of the barcode in Service mode according to instructions in Service - Diagnose, 2D Barcode, and send it to barcode@gambro.com

21. Exit Service mode.

SW update

1. Check that the machine is switched off.
2. Open the cabinet using an 8 mm Hex key.
3. Swing open the bracket mounted with protective and PIB board to access the PC-board.
4. Connect a PC keyboard to the PS2 connector on the PC 104 board.
5. Turn on the machine and insert the software upgrade CD into the CD-player.

Note! Software 7.xx requires PC-104 board (PCM-9375) to work.

6. Switch the main switch to OFF to restart the machine, wait 5 seconds and switch it ON again to boot from the CD.
7. A list with different boot setups is displayed.
8. Press 1 on the PC keyboard to start the software download – “Initiate all”.
9. A question appears; do you want to continue, press Y on the PC keyboard.
10. When the software upgrade is complete a message “Press any key to continue.” occurs.
11. Remove the software CD and PC keyboard.
12. Switch the main switch to OFF to restart the machine, wait 5 seconds and switch it ON again.

Calibrate the display

1. Make sure that the Prismaflex control unit is switched OFF before starting the procedure.

2. Open the back door using the 8 mm Hex tool.

3. Set the SW1 (Dip Switch 1), on the Carrier board, to the ON position.

4. Turn on the Prismaflex control unit and follow the instructions given on the screen.

5. Turn off the Prismaflex control unit when the message `Press STOP to convaliate the calibr.` appears or press *SET(S)*.

6. Set the switch SW1 (Dip Switch 1), to the OFF position.

Chapter 3

Technical Description

Contents

Prismaflex® Control Unit 3:2
Prismaflex® Control Unit Functions 3:2
Prismaflex® Control Unit Components 3:3
Front Panel Components 3:3
Rear Panel Components 3:14
Interior Components 3:16
Interior — Door (Closed hatch) 3:16
Interior — Door (Opened hatch) 3:18
Interior — Front 1 . . . . 3:20
Interior — Front 2 . . . . 3:22
Interior — Front 3 . . . . 3:24
Interior — Front 4 . . . . 3:26
Electrical Description 3:28
Internal Connections 3:28
Modules 3:31
Power Supply 3:33
Carrier Board 3:34
Control CPU 3:35
Protective CPU board 3:36
ARPS board 3:38
PIB board 3:40
Alarm light module 3:41
LVDS interface board 3:41
External RS232 board 3:41
External Ethernet board 3:41
External Remote Alarm Connector 3:42
Fluid pumps 3:42
Blood pump 3:42
Syringe pump 3:43
Loader 3:43
Scales 3:43
ABD assembly 3:44
Signals 3:45

Prismaflex® Control Unit

The Prismaflex control unit is pre-attached to a column and a base with casters. For installation see Installation Guide on page 2:1.

Prismaflex® Control Unit Functions

The Prismaflex control unit is a software-controlled device that performs the following functions:

- Loads and primes the Prismaflex disposable set automatically.
- Pumps blood through the blood flowpath of the Prismaflex disposable set.
- Delivers anticoagulant solution into the blood flowpath.
- Pumps sterile infusion solutions into the blood flowpath of the Prismaflex disposable set, according to therapy in use.
- Pumps sterile dialysate into the fluid compartment of the filter in CRRT therapies.
- Controls the patient fluid removal or plasma loss, according to the therapy in use.
- Monitors the system and alerts the operator to abnormal situations through alarms.

Prismaflex® Control Unit Components

The Prismaflex control unit components are divided into:

- Front Panel
- Rear Panel
- Interior Components

Front Panel Components

The front panel components of the Prismaflex control unit are illustrated and described in the following figures.

- Figure 3:1 on page 3:4 shows the pumps.
- Figure 3:2 on page 3:6 shows the pressure components.
- Figure 3:3 on page 3:8 shows sensors and clamps.
- Figure 3:4 on page 3:10 shows the scale components.
- Figure 3:5 on page 3:12 shows miscellaneous components.

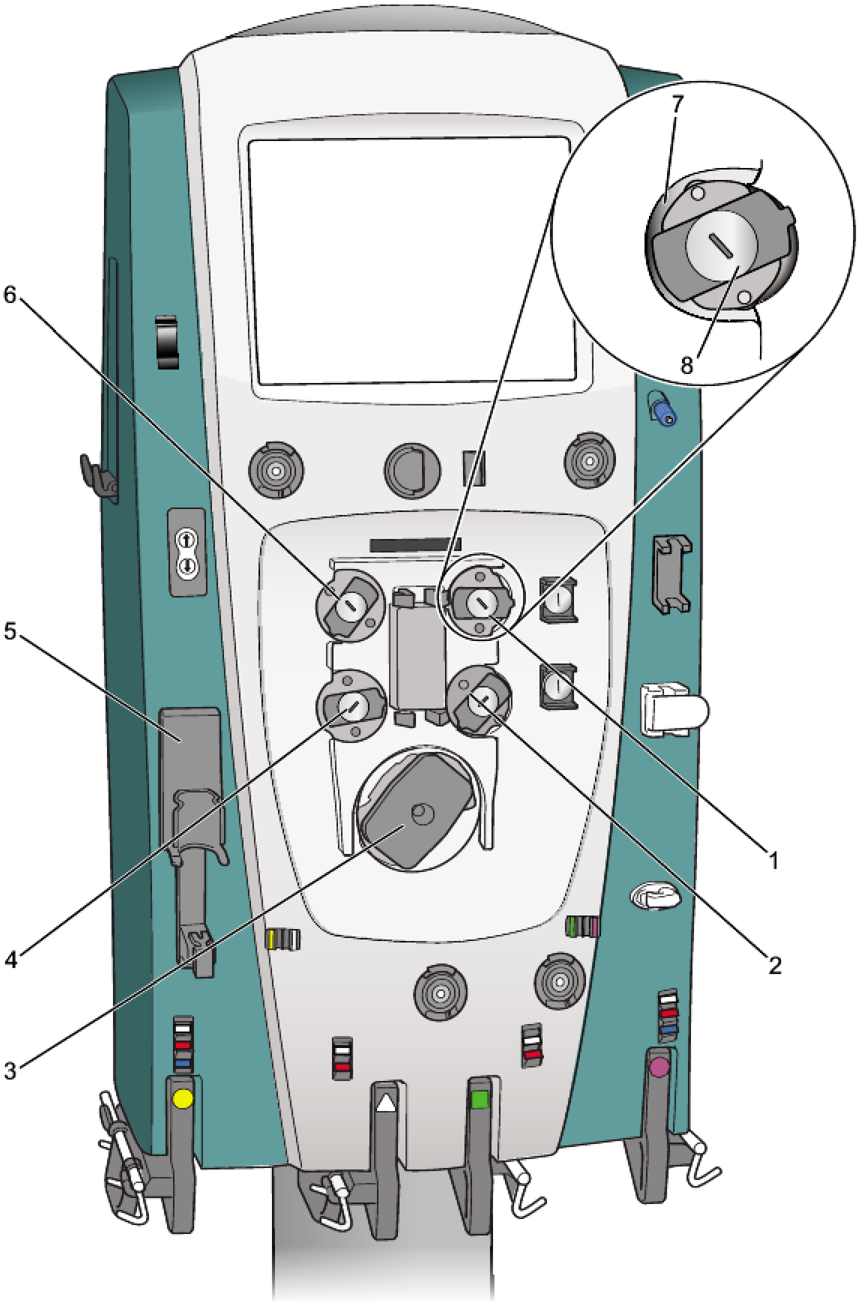


Figure 3:1 Pumps

1. **Dialysate/replacement 2 pump**
   CVVHD, CVVHDF: Pumps dialysate solution into the fluid compartment of the filter.

   CVVH: If post-filter replacement delivery has been chosen and replacement solution has been placed on the green scale, this pump delivers replacement solution into the post-filter blood flowpath.

2. **Replacement pump**
   Pumps replacement solution/fluid into the blood flowpath.

   CRRT: Replacement solution can be delivered either pre- or post-filter.

   TPE: Replacement fluid is always delivered 100% post filter.

3. **Blood pump**
   Pumps blood through the blood flowpath of the Prismaflex disposable set.

4. **Pre-blood pump (PBP)**
   If required, pumps a solution into the blood access line at a location immediately after patient blood enters the line and before the blood pump.

   In “Citrate – Calcium, Prismaflex syringe pump” anticoagulation the PBP is the pump infusing the citrate solution into the blood access line.

5. **Syringe pump assembly**
   The pump assembly holds the solution-filled syringe and controls the rate of delivery. Delivery can be continuous or in boluses.

   In “Systemic, Prismaflex syringe pump” anticoagulation method, the syringe pump delivers anticoagulant into the blood flowpath.

   In “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method, the syringe pump delivers calcium solution into patient via a separate central venous access.

6. **Effluent pump**
   CRRT: Pumps ultrafiltrate/dialysate; automatically controls the ultrafiltration rate, based on the operator-set patient fluid removal rate, PBP, dialysate, replacement, and syringe flow rates (if applicable).

   TPE: Pumps removed plasma; automatically controls the plasmafiltration rate based only on the operator-set patient plasma loss and replacement fluid rates. PBP and syringe flow rates are not considered in the effluent pump rate.

7. **Pump raceway**
   Tubing pathway within each peristaltic pump. The raceways accept the pump segments of the Prismaflex disposable set.

8. **Rotor**
   Center component of each peristaltic pump that rotates during pump operation. Holds two rollers that occlude the pump segment in the raceway. Occlusion moves the fluid in the pump segment forward in discrete amounts and prevents backflow.

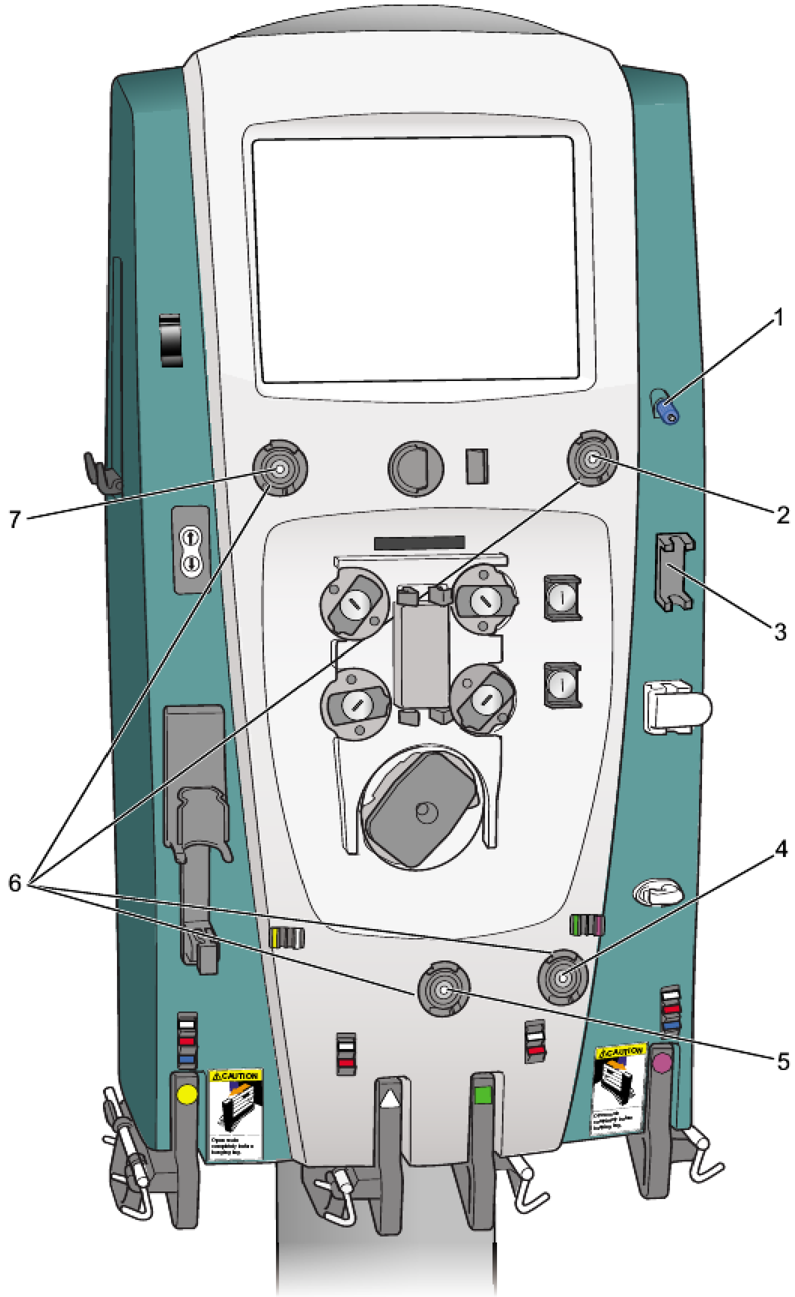


Figure 3:2 Pressure components

1. **Return pressure port**
   Connects to the monitor line of the deaeration chamber on the Prismaflex disposable set. A pressure sensor (transducer) located behind the pressure port enables noninvasive pressure monitoring of the return line and deaeration chamber. A fluid barrier at the distal end of the monitor line protects the return pressure sensor from accidental blood entry.

2. **Effluent pressure pod**

3. **Deaeration chamber holder**
   Holds the deaeration chamber of the Prismaflex disposable set.

4. **Filter pressure pod**

5. **Access pressure pod**

6. **Pressure sensor housings**
   Housings that hold the pressure pods of the Prismaflex disposable set. A pressure sensor (transducer) is located behind each housing. The sensors and pressure pods enable noninvasive pressure monitoring of the access, filter, and effluent lines. There are no air-blood interfaces.

7. **Pressure pod (not used, for future therapy)**

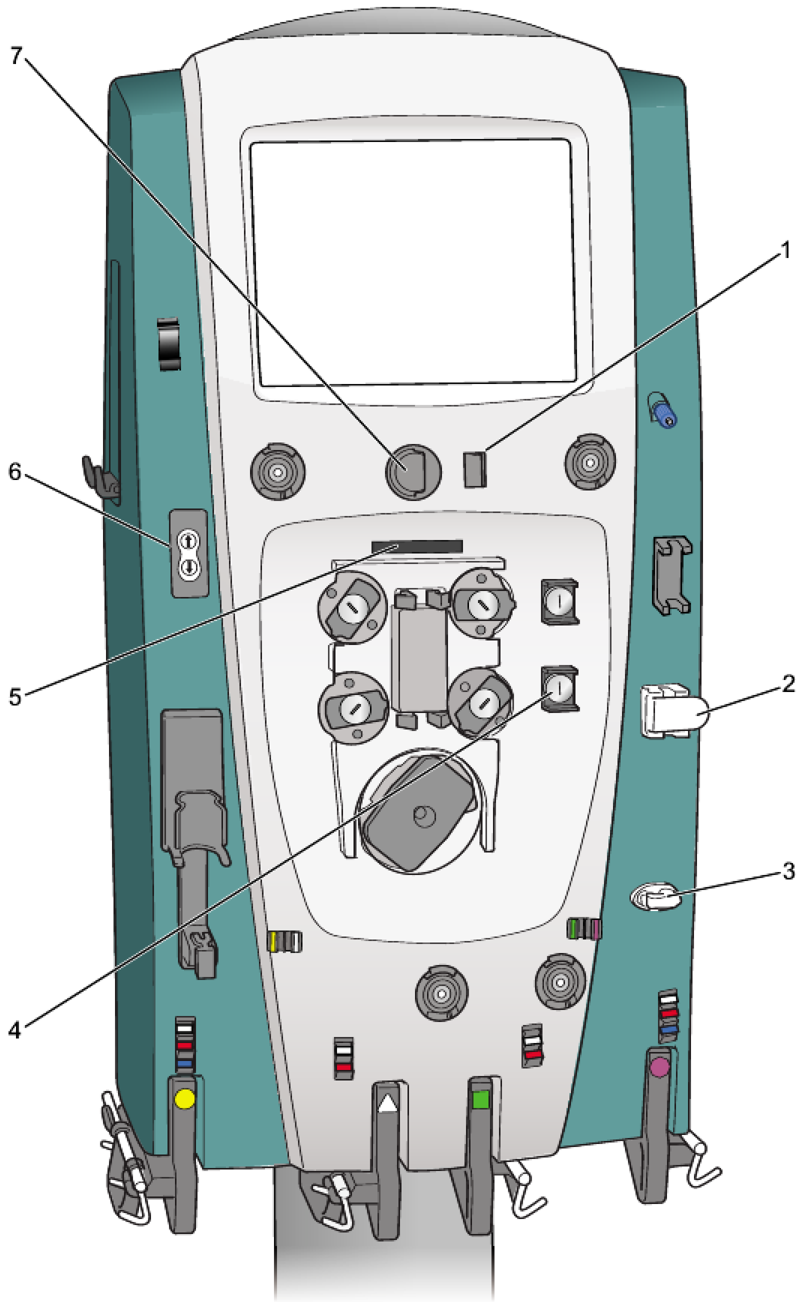


Figure 3:3 Sensors and clamps

1. Discharger ring guide

Holds the electrostatic discharger ring of the Prismaflex disposable set. The main function of the discharger ring is to lower the voltage potential in the blood/fluid path. As a result, artifacts on cardiac monitors will be minimized.

Always install the discharger ring in its guide before connecting a patient to the Prismaflex disposable set.

2. Air bubble detector (housing also has a tubing detection switch and a patient blood sensor)

Ultrasonic transmission/detection device that continuously monitors the return line for air bubbles. A Warning alarm occurs if a bubble is detected.

Tubing detection switch (physically moves down when tubing is installed).

Patient blood sensor (infrared sensor that detects if blood is in the tubing).

3. Return line clamp (assembly also has a tubing detection switch)

Occlusive clamp that closes during all Warning and Malfunction alarms, when power is off, and during some self-tests. Prevents blood and/or air from passing to the patient.

For patient safety, a tubing detection switch is also located in the return clamp assembly. The switch physically moves down when tubing is correctly installed under the clamp.

4. Pinch valves (upper and lower)

CVVH, CVVHDF: Upper pinch valve accepts tubing coming from the dialysate/replacement 2 pump; lower pinch valve accepts tubing coming from the replacement pump. The valves open/close automatically to allow pre- and post-filter options for delivery of replacement solution.

5. Bar code reader

The bar code reader that decodes the bar code on the Prismaflex disposable set during the set loading procedure. With this information, Prismaflex software accesses the default alarm limits, flow rate ranges, and priming sequence for the set that is loaded.

6. Syringe control panel

Consists of UP and DOWN buttons that allow installation and removal of the syringe. The buttons are activated/inactivated by Prismaflex software, depending on operating conditions.

7. Blood leak detector

Continuously monitors the effluent line for the presence of red blood cells, indicating a leak in the filter membrane. A warning alarm occurs if red blood cells are detected.

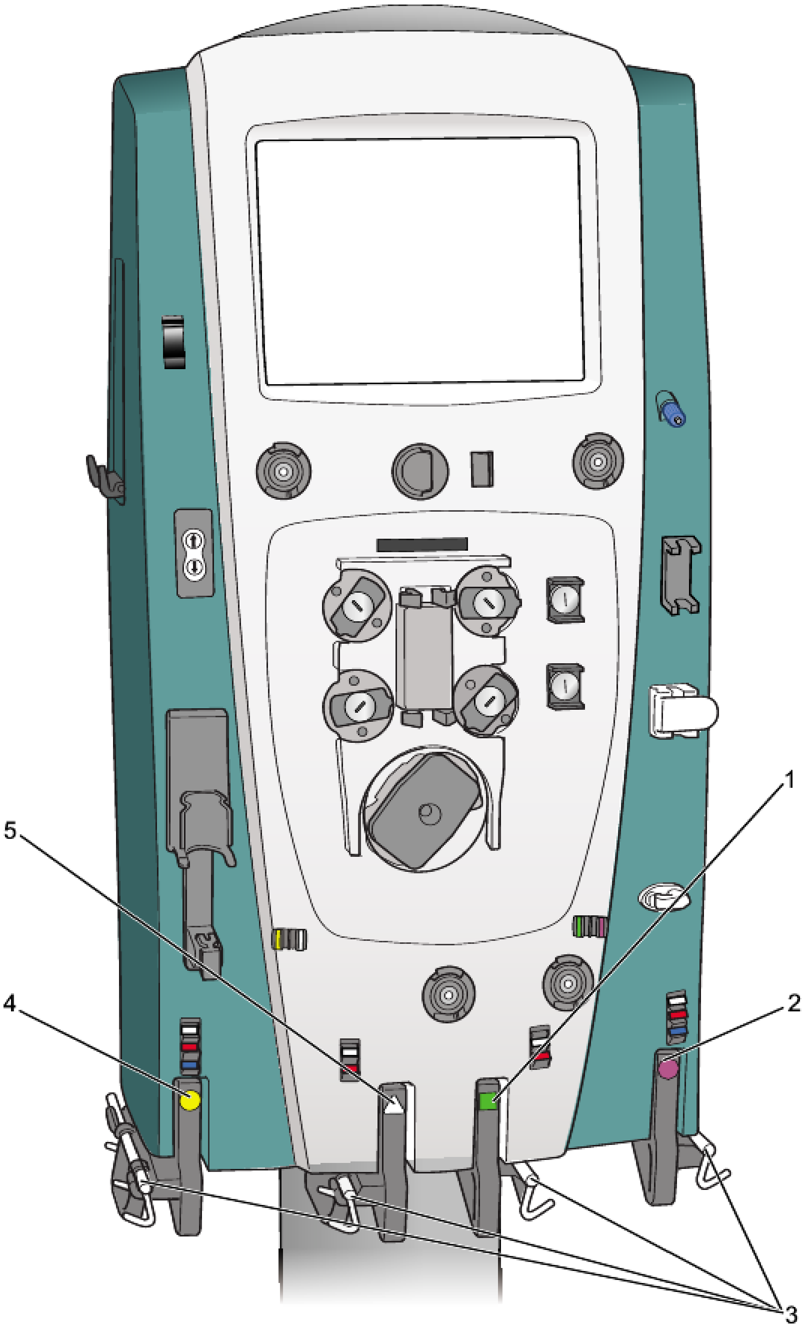


Figure 3:4 Scale components

1. **Dialysate scale (green square)**

2. **Replacement scale (purple octagon)**

3. **Scale carrying bar assembly**
   The bar tray on each scale holds a removable carrying bar with three hooks. Using a table or other support, bags may be attached to/removed from the hooks. After the carrying bar is replaced in the bar tray, it must be rotated so the handle is toward the floor, so the scale can be properly closed.
   Various sizes of bags can be used, depending on the scale.

4. **Effluent scale (yellow circle)**

5. **PBP scale (white triangle)**

6. **General scale Information**
   Independently monitor fluid bag/container weights. Weight is used by Prismaflex software to precisely control solution flow rates and patient fluid removal /plasma loss. An alarm sounds when the PBP, dialysate and replacement solution bags/containers are nearly empty, or when the effluent bag is nearly full.
   The operator pulls the bar tray of a scale out (away from) the control unit to attach or remove bags/containers. When the tray is pulled out, the scale is in "open" position; when the tray is completely pushed in, the scale is in "closed" position. An alarm sounds if the scale is open when operating conditions require it to be closed.

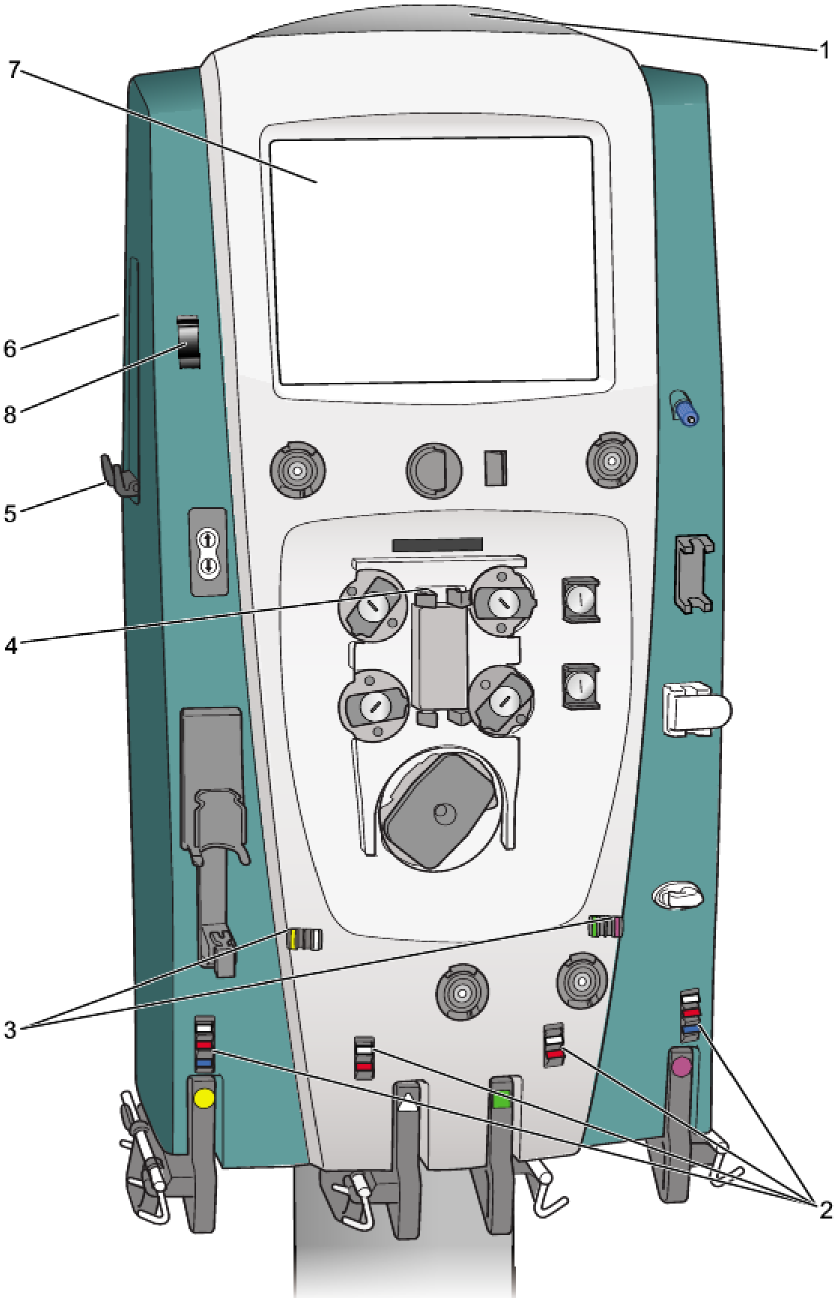


Figure 3:5 Miscellaneous components

1. **Status light**
   Lights up to give a general indication of operating conditions.

   Green constant light: Indicates that all monitored parameters are normal during administration of the treatment (Run mode).

   Yellow constant light: Indicates that an Advisory alarm has occurred, or an alarm has been overridden. Immediate patient safety is not compromised, but the operator should investigate (Run mode).
   Note: During modes in which a patient treatment is not in progress (Setup, Standby, End, and Custom mode), yellow indicates that monitoring is active, and that all monitored parameters are normal.

   Yellow flashing light: Indicates that a Caution alarm has occurred. Immediate patient safety is not compromised, but the operator should investigate (Run mode).

   Red flashing light: Indicates that a Warning or Malfunction alarm has occurred because of a condition of possible patient hazard. Immediate operator intervention is required (Run mode).

2. **Tubing clips**
   Secure the blood lines going to the patient, including the PBP line. Route tubing through clips closest to patient, according to color coding.

3. **Tubing guides**
   Hold the lines of the Prismaflex disposable set in correct position on the control unit. The color of each tubing guide matches the color of the line it holds.

4. **Loader**
   Loads the Prismaflex disposable set.

5. **Side hooks (left and right side)**
   Bags can be put on this hook.

6. **Recessed handles (left and right side)**

7. **Display**
   Shows text and softkeys. Provides operating, alarm, and help instructions. Pressing the softkeys allows the operator to change settings, start and stop functions, and navigate between screens.

8. **Upper clip**
   Supports the calcium infusion line when performing “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method. Temporarily holds the return line during setup of hemopurification sets.

Rear Panel Components

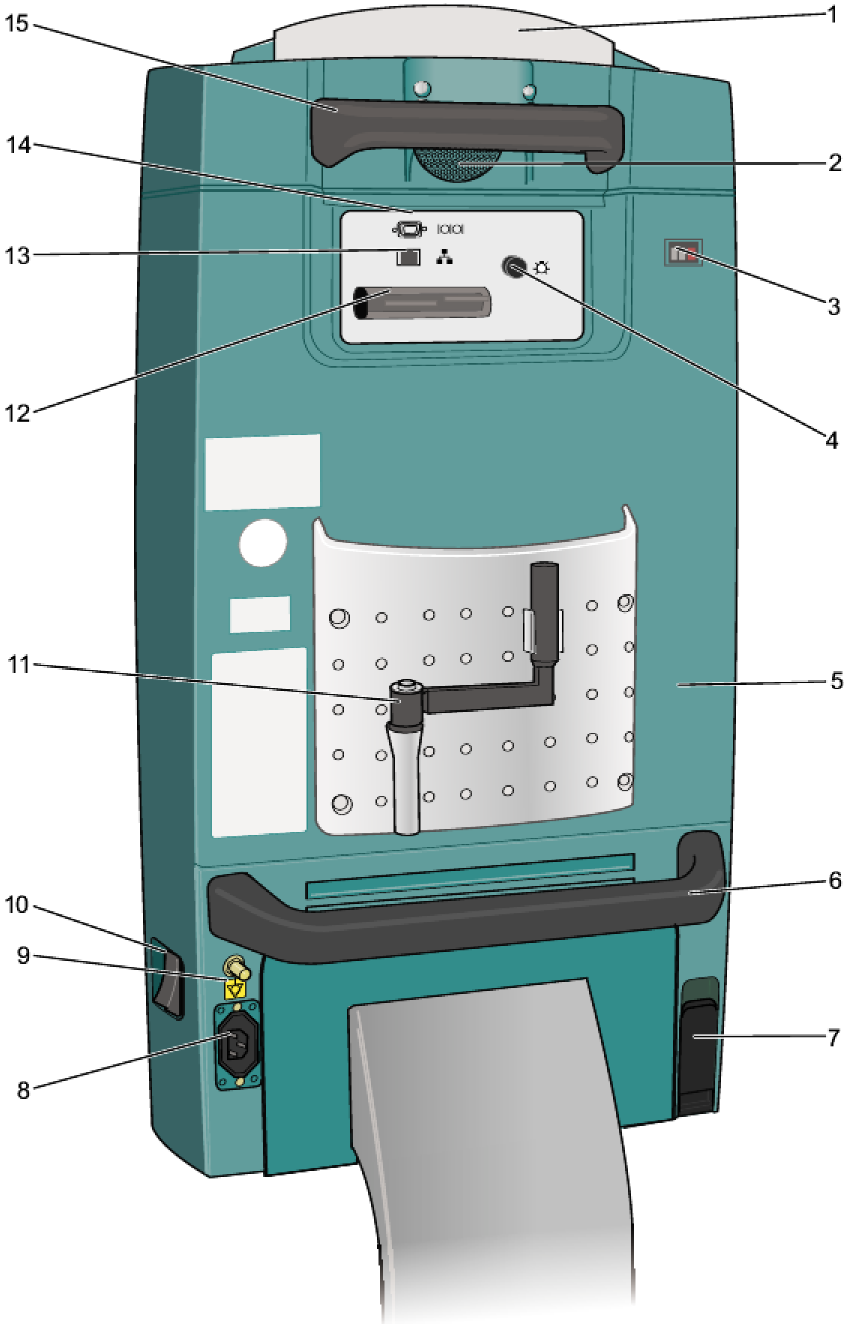


Figure 3:6   Prismaflex control unit: Rear Panel

1. Speaker
Creates alarm sounds.

2. Fan
Provides continuous ventilation for the interior components of the control unit.

3. Hour meter
Displays operating hours (cumulative time that power to the Prismaflex control unit has been on).

4. **Remote alarm connection**
   Connection for an optional remote alarm (for example installed in a nursing station).

5. **Buzzer (inside)**
   Transmits a continuous buzz if a power loss occurs.

6. **Rear handle (bottom)**

7. **Power cord holder**

8. **Power cord socket**

9. **Connection for potential equalization conductor**
   Potential equalization terminal is connected to the monitor chassis. It can be connected to corresponding terminals on other equipment to eliminate potential differences. Do not use it for additional protective grounding.

10. **Power switch**

11. **Pump crank**

12. **Technical data card holder**
    You can copy history data to a technical data card.

13. **Ethernet port**
    An IP addressable port for data exchange with a personal computer or communication network. Network communication ability is only intended for sending out data and will not receive data that changes the settings in the Prismaflex control unit.

14. **RS232 serial communication port**
    For data exchange with a personal computer, communication network or modem. Network communication ability is only intended for sending out data and will not receive data that changes the settings in the Prismaflex control unit.

15. **Rear handle (top)**

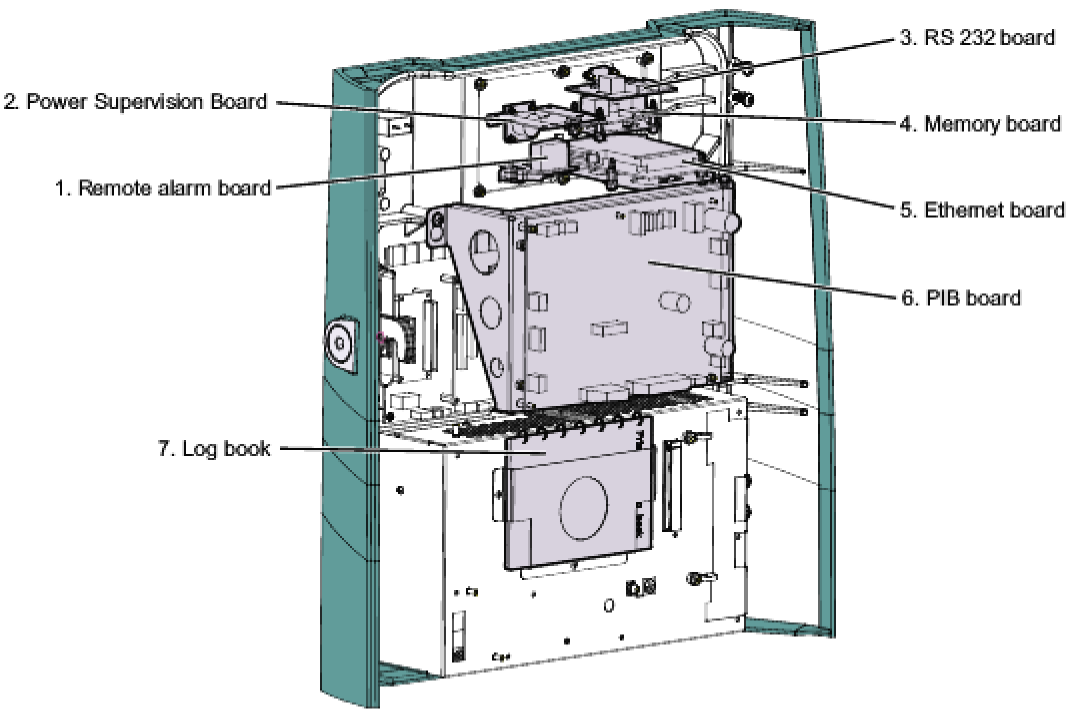
Interior Components

Only authorized service technicians have access to the interior of the Prismaflex control unit and are allowed to perform service maintenance on the Prismaflex control unit.

This section is divided into:

- Door
- Front

Interior — Door (Closed hatch)



1. **Remote alarm board**
   For use with external alarms.

2. **Power Supervision Board**
   Power Supervision board detects unintended switch off during treatment.

3. **RS 232 board**
   Enables external serial data communication with the Prismaflex control unit.

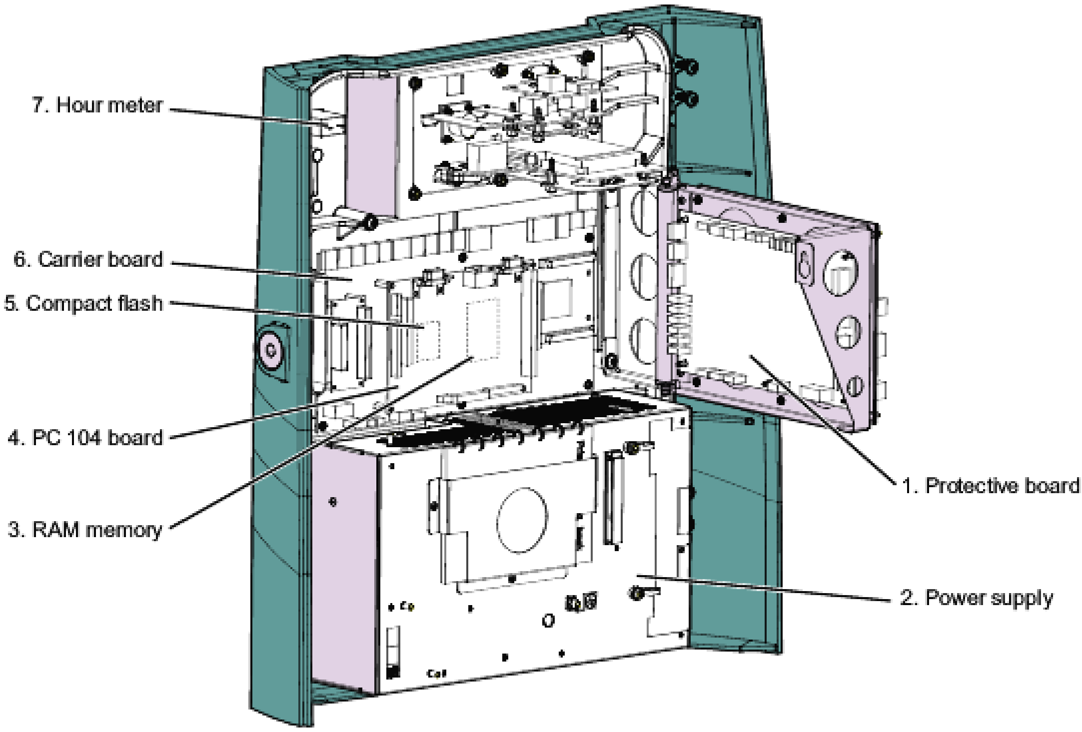
4. **Memory board**
   Prismaflex control unit interface for the technical data card.

5. **Ethernet board**
   Enables external Ethernet communication with the Prismaflex control unit.

6. **PIB board**
   Peripheral Interface Board. Contains the circuitry and connections for the UABD, venous clamp, BLD and the pinch valves.

7. **Log book**
   Update the Prismaflex control unit log book when the service is performed.

Interior — Door (Opened hatch)



1. **Protective board**
   Controls the Protective system.

2. **Power supply**
   Supplies DC voltage to the Prismaflex control unit.

3. **RAM memory**
   Internal memory for the PC 104 board.

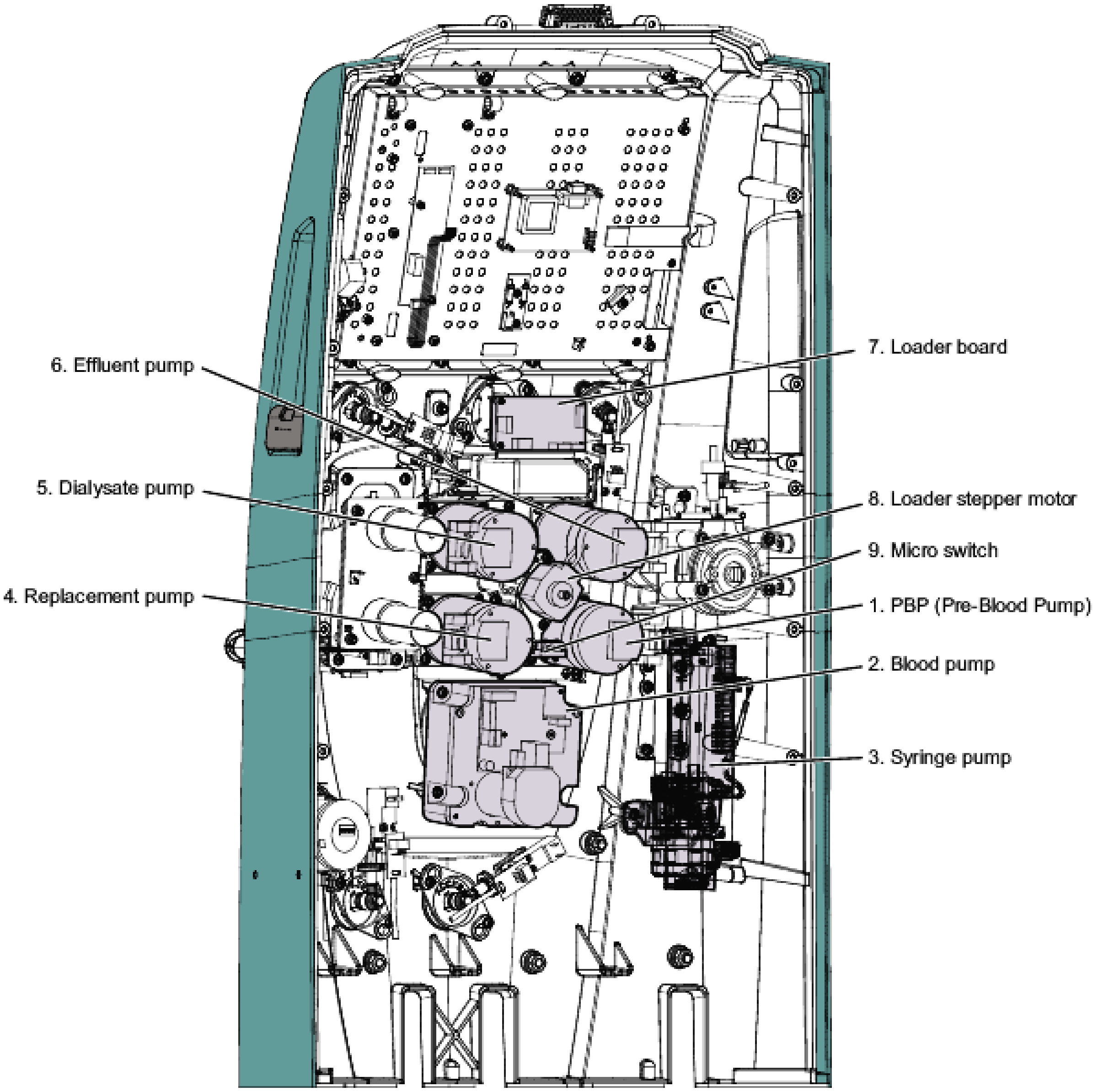
4. **PC 104 board**
   Control system CPU.

5. **Compact flash**
   Placed on backside of PC 104 board, stores the Prismaflex software.

6. **Carrier board**
   Interface for the PC 104 board.

7. **Hour meter**
   Counts the total running hours of the Prismaflex control unit. Not only the treatment hours.

Interior — Front 1



1. **PBP (Pre-blood pump)**
   A stepper motor runs the slave pump rotor which rotates the PBP pump.

2. **Blood pump**
   Runs the Blood pump rotor.

3. **Syring pump assembly**
   Administrates the syringe fluids.

4. **Replacement pump**
   A stepper motor runs the slave pump rotor which rotates the replacement pump.

5. **Dialysate pump**
   A stepper motor runs the slave pump rotor which rotates the dialysate pump.

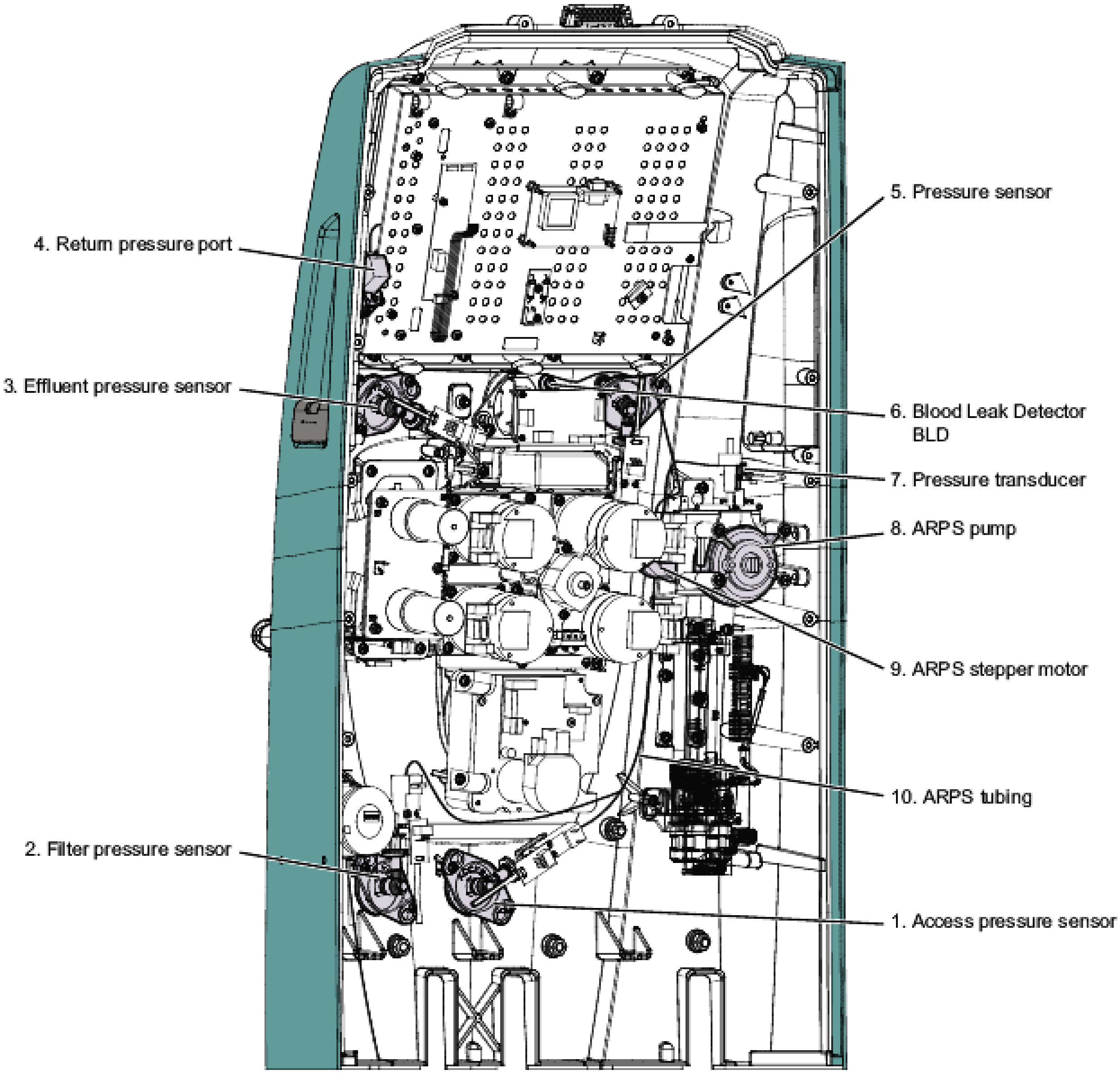
6. **Effluent pump**
   A stepper motor runs the slave pump rotor which rotates the Effluent pump

7. **Loader board**
   Controls the loader stepper motor.

8. **Loader stepper motor**
   Maneuvers the loader.

9. **Micro switch**
   Detection for completely loaded Prismaflex disposable set.

Interior — Front 2



1. **Access pressure sensor**

2. **Filter pressure sensor**
   Cable length 50 cm

3. **Effluent pressure sensor**
   Cable length 100 cm

4. **Return pressure port**

5. **Pressure sensor**
   Fifth pod. Not used, for future therapy. Cable length 70 cm

6. **Blood Leak Detector BLD**
   Infrared blood leak detection (detects presence of red blood cells in the effluent line).

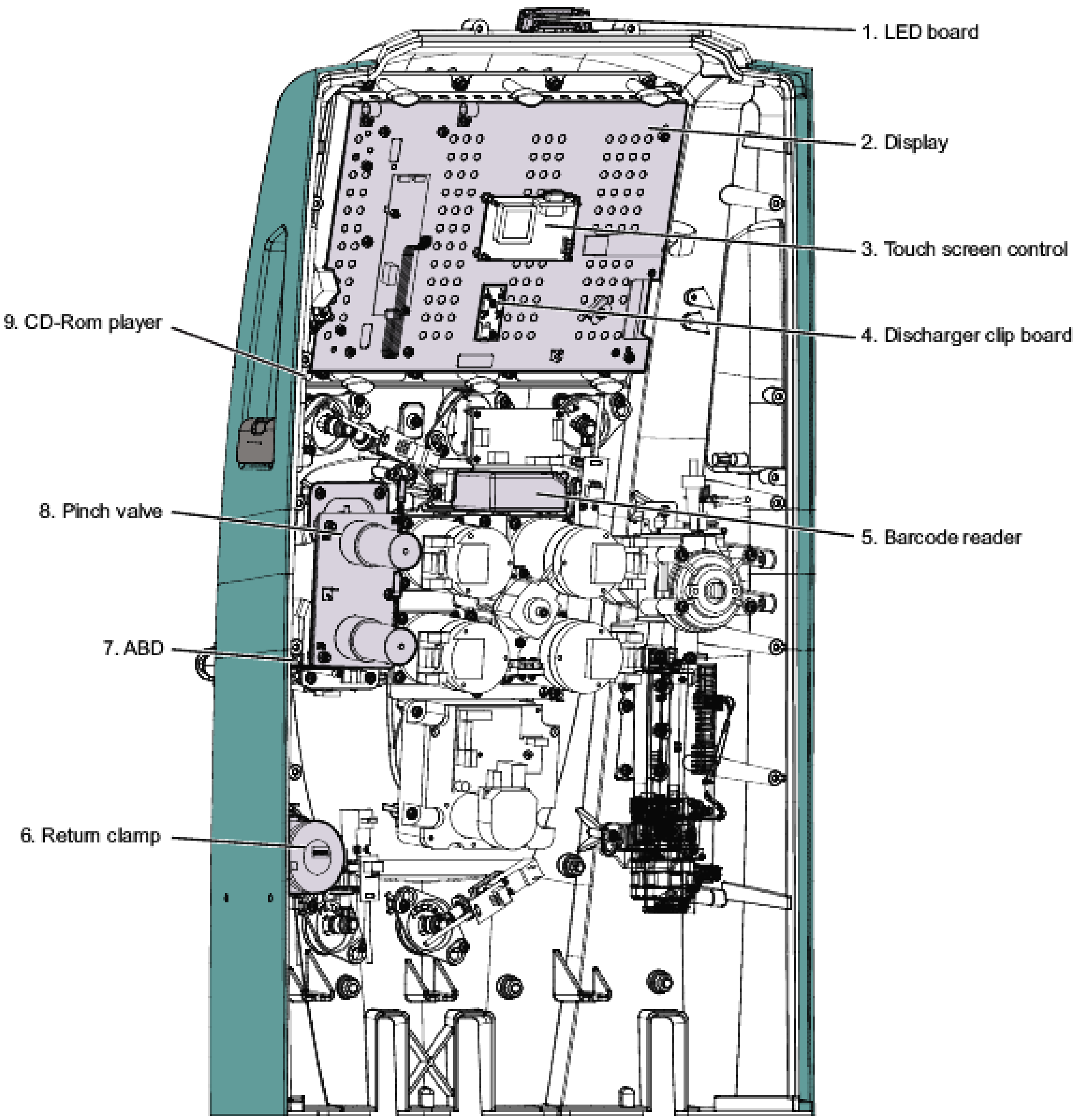
7. **Pressure transducer**
   Measures reference pressure for the ARPS (Automatic Repositioning System).

8. **ARPS pump**
   The pump is used for the ARPS and for adjusting the level in the bubble trap.

9. **ARPS stepper motor**
   The motor is used for the ARPS and for adjusting the level in the bubble trap.

10. **ARPS tubing**
    Connects the complete pressure system.

Interior — Front 3



1. **LED board**
   Alarm light-green, yellow and red

2. **Display**
   Graphical user interface.

3. **Touch screen control**
   Handles the information from the touch screen.

4. **Discharge clip board**
   Connects the discharger clip to earth.

5. **Bar code reader**
   Recognizes the filter set loaded on the Prismaflex control unit.

6. **Return clamp**
   The return clamp has two functions:

   - Clamps the return line.

   - Tubing detection switch.

7. **Air Bubble Detector ABD**
   The ABD has three functions:

   - Ultrasonic transmission/detection (device that continuously monitors the return line for air bubbles. A Warning alarm occurs if a bubble is detected).

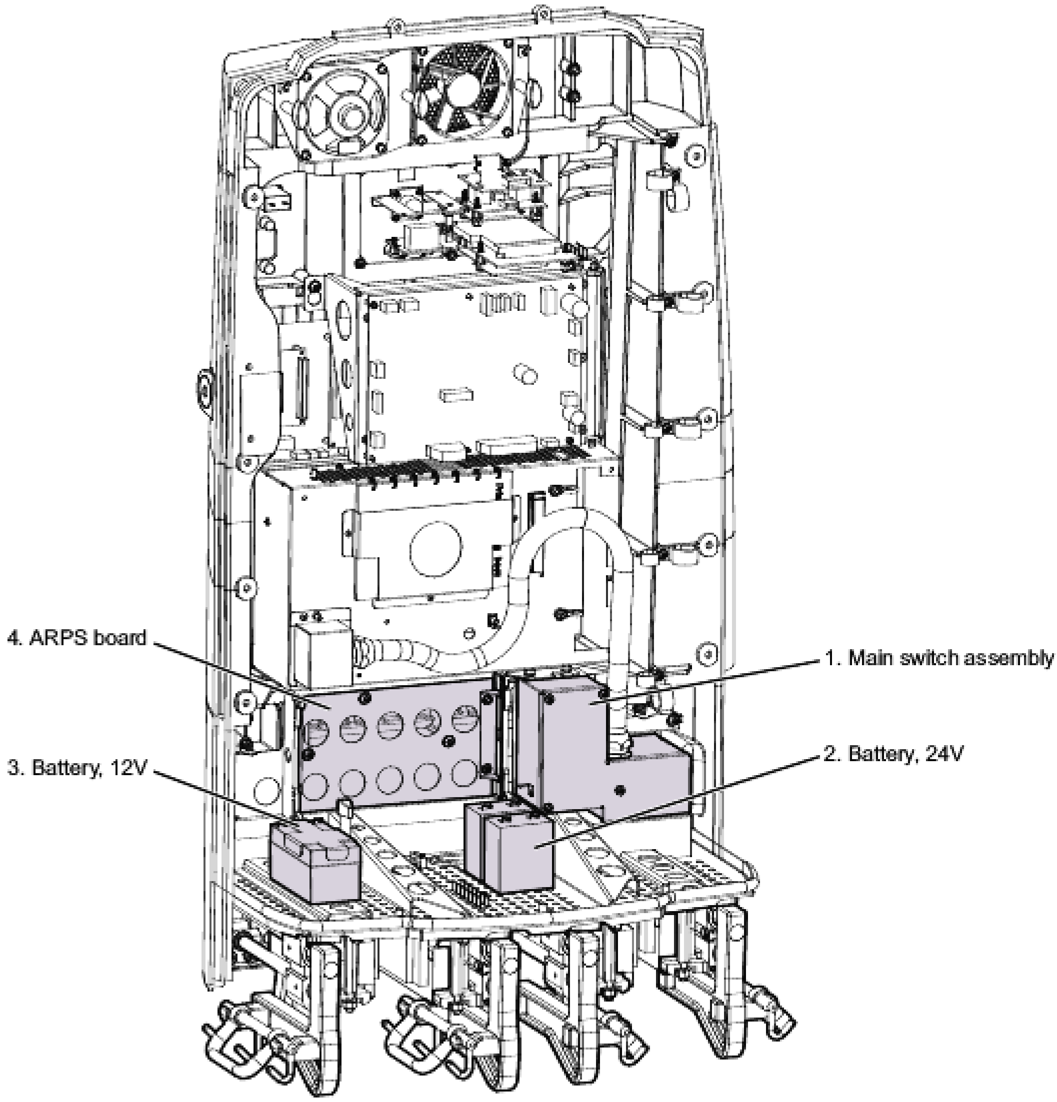
   - Tubing detection switch.

   - Infrared patient sensor. (Not used)

8. **Pinch valve**
   The pinch valves open/close, depending on which therapy is chosen, to allow pre- and post-filter options for delivery of replacement solution.

9. **CD-Rom player**
   CD/DVD reader

Interior — Front 4



1. **Main switch assembly**

2. **Battery, 24 V**
   Provides the possibility to proceed treatment during a power failure. For more information see Power Failure on page 5:101.

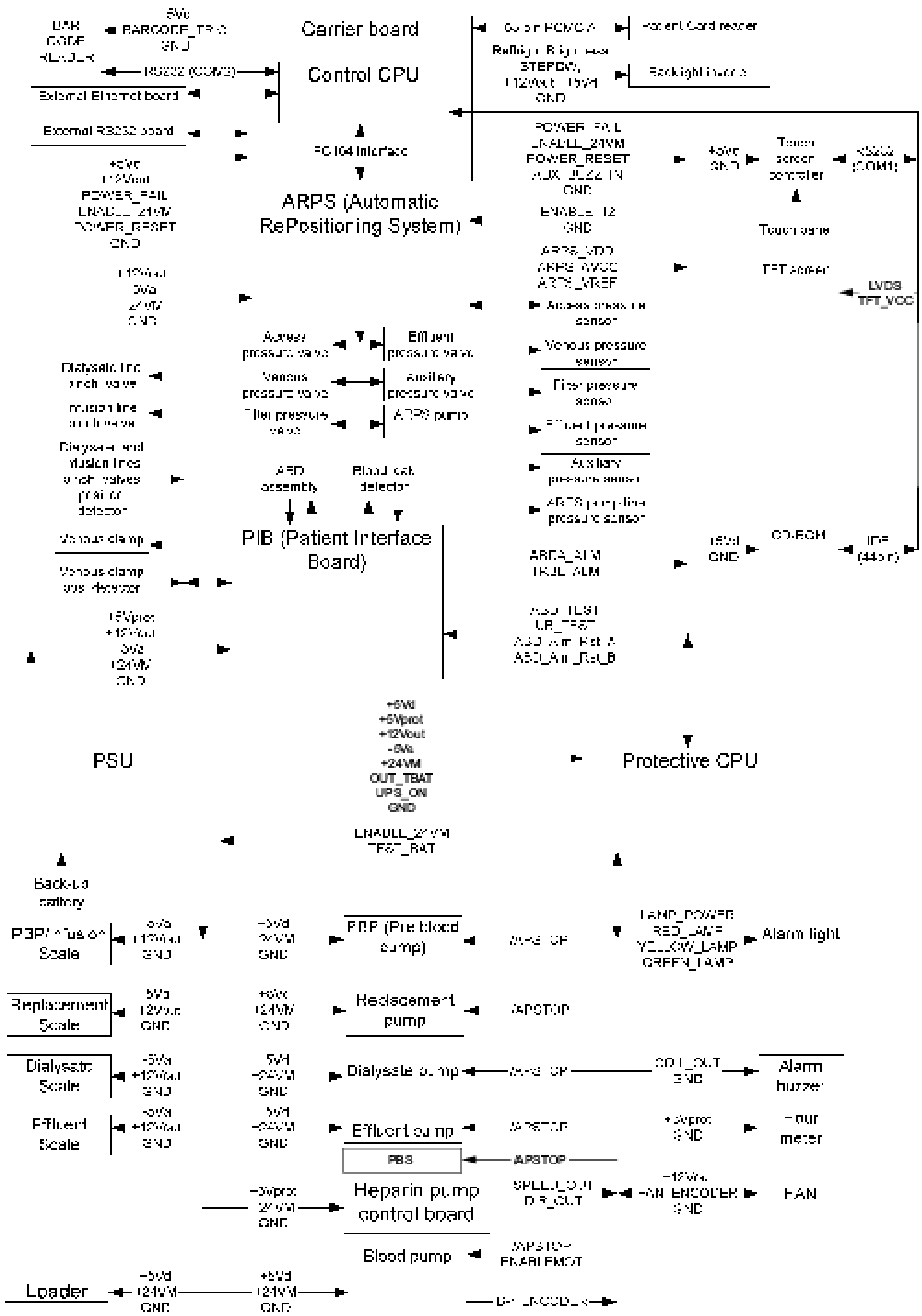
3. **Battery, 12 V**
   Not present in newer configurations of the Prismaflex control unit.

4. **ARPS board**
   All pressure sensors and the ARPS valves are connected to this board.

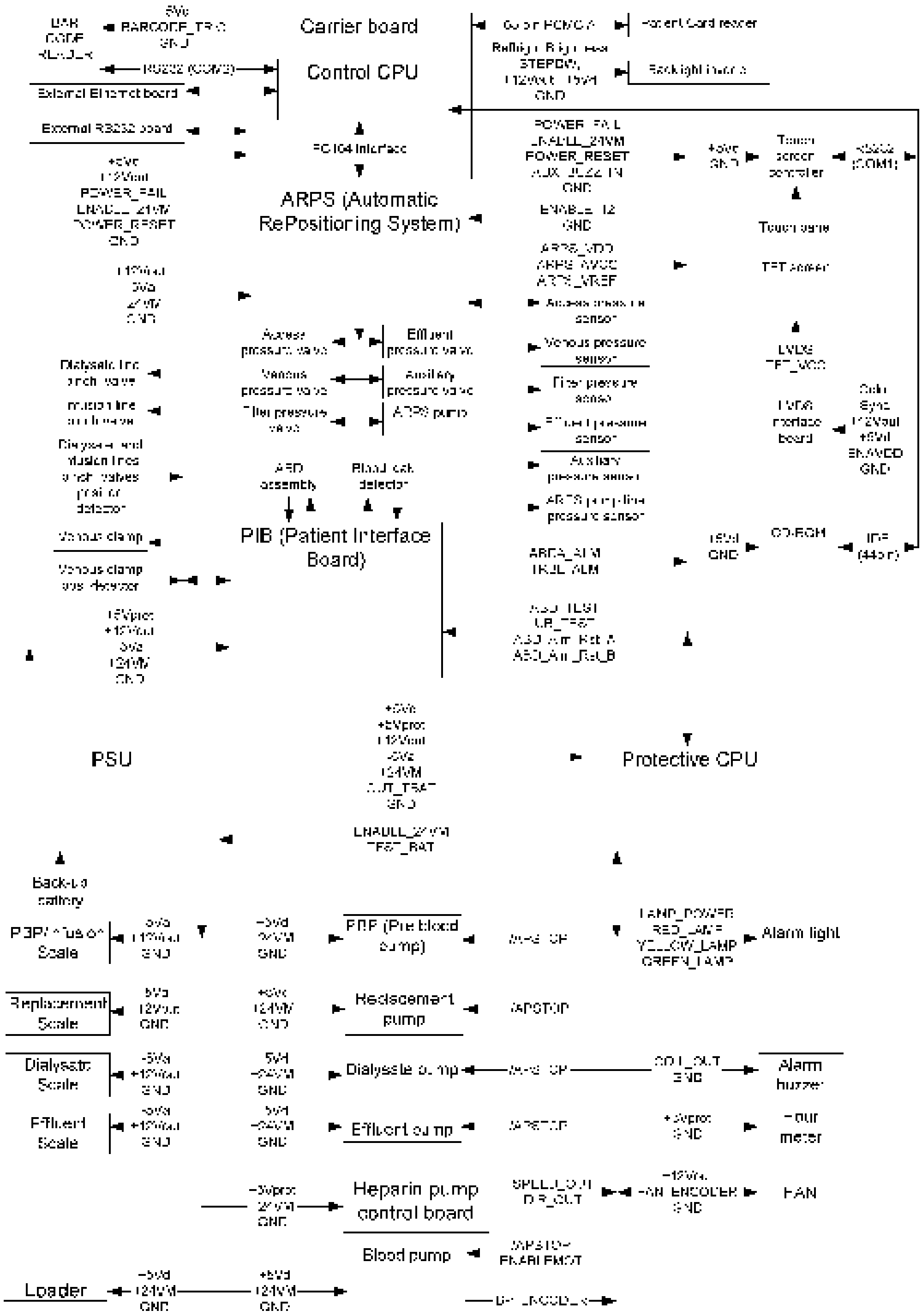
Electrical Description

Internal Connections

The figures below shows the internal connections between boards.

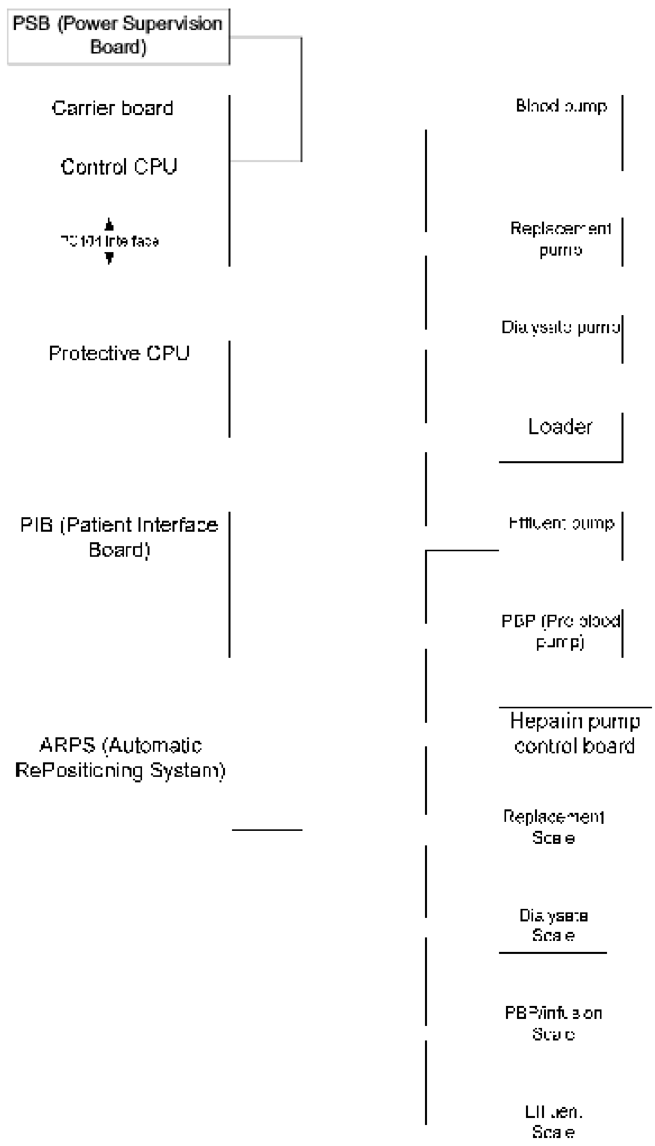


Internal Connections (Display with integrated LVDS)



Internal Connections (Display with out integrated LVDS)

The figures below shows the routing for the internal I2C communication. Each board except the Blood pump has two I2C connectors connected in parallel. Buffering is made on each board using an I2C line driver type Philips 82B715. The I2C bus consists of 4 signals (+5V, SDA, SCL and GND). The +5V supply is connected to the Blood pump board, but it is possible (through jumpers on each board) to set a different configuration of the +5V supply.



I2C Interconnection Diagram

Modules

The electronic design consists of the following main modules:

- Power supply unit (PSU)
- Protective CPU board
- Carrier board (working as motherboard for the Control CPU)
- Control CPU (PC-104)
- ARPS board
- PIB board

Supporting and connected modules are:

- Slave fluid pumps
- Blood pump
- Syringe pump
- Loader
- Scales
- ABD assembly
- Blood leak detector
- Pinch valves
- Venous clamp
- Pressure valves
- Pressure sensors
- Bar-code reader
- Technical data card holder
- Remote alarm
- External RS232 & Ethernet boards
- Power supervision board

- LVDS interface board
- Touch screen controller
- TFT display with backlight inverter and touch screen
- Alarm light and buzzer
- Hour meter

Power Supply

The power supply provides the following DC voltages referred to a common ground:

Voltage	Low limit	High limit	Nominal current	Description
+24Vm	22.8V	25.2V	15A (shared with currently unused +24Vc)	Positive 24V used as supply mainly to actuators. This voltage is enabled by the signal ENABLE_24Vm from the Protective CPU board. When the PSU is running on battery in 24V mode (UPS mode) these limits can be ignored and the voltage might follow the battery voltage (max 1V below battery voltage)
+12Vout	11.9V	12.3V	4.0A	Positive 12V used for supply of analogue parts as well as the ARPS pump
+5Vd	5.1V	5.3V	6A	Positive 5V generally used for digital circuitry
+5Vprot	5.1V	5.3V	5A	Positive 5V used for digital circuitry in the protective system and also used for miscellaneous digital circuitry
–5Va	–5.4V	–5.1V	2.0A	Negative 5V used as supply to analogue parts

The system reference ground is in the power supply unit, and all sub-system grounds originate from here to avoid ground loops as well as power noise on sensor signals.

Description	Signals	Interfacing board(s)/module(s)
Protective CPU supply & PSU voltage supervision	+5Vd, +5Vprot, +12Vout, –5Va, +24Vm, GND	Protective CPU board
Enable of actuator power	ENABLE_24Vm	From Protective CPU board
Carrier board (Control CPU) supply & PSU status	+5Vd, +12Vout, POWER_FAIL, POWER_RESET, ENABLE_24Vm, GND	Carrier board (signals POWER_FAIL, ENABLE_24Vm and POWER_RESET are passed by the Carrier board to the Protective CPU)
ARPS supply	+12Vout, –5Va, +24Vm, GND	ARPS board
PIB supply	+5Vprot, +12Vout, –5Va, +24Vm, GND	PIB board
Slave pump & Loader supply	+5Vd, +24Vm, GND	PBP/Infusion pump, Replacement pump, Dialysate pump, Effluent pump, Blood pump and Loader
Syringe pump supply	+5Vprot, +24Vm, GND	Syringe pump control board
Scales supply	+12Vout, –5Va, GND	PBP/Infusion scale, Replacement scale, Dialysate scale and Effluent scale
Back-up battery test	TEST_BAT	From Protective CPU board
Battery test status	OUT_TBAT	To Protective CPU board

Carrier Board

The Carrier board has the following main functions:

- Motherboard for the Control CPU
- Backlight inverter control for user interface TFT screen
- Provides I2C communication to the PC-104 compatible Control CPU
- Contains a 512kB battery backed-up memory for storage of data from therapies, events and alarms (384kB) and used for communication and for the PCMCIA controller supporting the Technical data card interface

Description	**Signals**	**Interfacing board(s)/module(s)**
Power input	+5Vd, +12Vout, GND	From PSU
Power status	POWER_FAIL, POWER_RE-SET, ENABLE_24Vm and GND	From PSU To Protective CPU board
Interface to Control CPU	16-bit ISA-bus PC-104 signals	Control CPU board
External RS232	Rx, Tx, RTS, CTS, +5Vd, GND	External RS232 interface board
LCD backlight inverter power and control	+12Vout, +5Vd (NC), Brightness, Refhigh (NC), STEPDW and GND	To LCD backlight inverter (STEPDW enables inverter)
Bar-code reader power and control	+5Vd, BARCODE_TRIGGER and GND	To Bar code reader module (BARCODE_TRIGGER enables bar code reader LED)
Technical Data Card Reader	68 pin PCMCIA interface	To PCMCIA holder
Control CPU buzzer request	AUX_BUZZ_IN, GND	To Protective CPU board
I2C bus	+5Vd, I2C_SDA, I2C_SCL, GND	Protective CPU board

Control CPU

The Control CPU is a PC-104 compatible PC with a Pentium processor industrial standard. VxWorks is used as Operating System. The Control CPU has the following main functions:

- Runs the treatment (including priming and end-of-treatment etc.)
- Supervises the behaviour of the Prismaflex control unit
- Controls the subsystems ARPS and PIB as well as fluid pumps, Blood pump, Syringe pump, scales and loader (through I2C)
- Managing requests from Protective system (through I2C)
- GUI control
- Provides connection to external Ethernet interface
- Supports the Touch screen controller through RS232 / COM1
- Supports the Bar-code reader through RS232 / COM2
- Supports the CD-ROM through IDE

Description	**Signals**	**Interfacing board(s)/module(s)**
Connection to motherboard	16-bit ISA-bus PC-104 signals	Carrier board
Touch screen interface	Full RS232 interface on Control CPU COM1	Touch screen controller
Bar-code reader interface	RS232 interface (Rx and Tx) on Control CPU COM2	Bar-code reader
TFT output	44-pin connector	LVDS transmitter board. Present only on older Prismaflex control units. (See Service Newsletter for Prismaflex control unit numbers)
CD-ROM interface	40 signals on 44-pin connector standard IDE-cable	CD-ROM player
External Ethernet	IRX–, IRX+ ITX– and ITX+	External Ethernet board

Protective CPU board

The Protective CPU board has the following main functions:

- Monitors the activity of the Prismaflex control unit and forcing the Prismaflex control unit in a Safe State through a specific state request to the Control System in case of mismatch with the appropriate Safety Criteria
- Activates of tests T0 and T1 to monitor the Hardware integrity (T0 and T1 are standards for electrical/mechanical safety for medical device)
- Request the control system to activate Specific Safe State conditions
- Activates the General Safe State if previous specific safe state condition was not met or if a severe failure condition occurred
- Supervises PWR_FAIL and PWR RESET signals
- Supervises all supply voltages (both from PSU and from ARPS)
- Handle the air bubble alarm
- Supervises the scales (through I2C)
- Supervises (directly) the speeds for Blood pump and Syringe pump
- Supervises (through I2C) the speeds for Dialysate pump, Effluent pump, Infusion pump and additional PBP (Pre-blood pump)
- Supervises (through I2C) the Access pressure, Return pressure, Filter pressure, Effluent pressure, Auxiliary pressure and ARPS pump line pressure
- Activates the alarm lights and speaker
- Activates remote alarm
- Enables the Blood pump relay
- Enables the +24V for pumps
- Enables the +12V for ARPS actuators
- Back-up battery test and monitoring

Description	Signals	Interfacing board(s)/module(s)
PSU voltage supervision	+5Vd, +5Vprot, +12Vout, –5Va, +24Vm, GND	From Power Supply Unit (PSU)
PSU status monitoring	POWER_FAIL, ENABLE_24Vm, POWER_RESET, GND	From Carrier board
Enable of actuator power	ENABLE_24Vm	To PSU
ARPS board actuator power control	ENABLE_12, GND	To ARPS board
ARPS board voltage monitoring	VDD_ARPS, AVCC_ARPS, VREF_ARPS	From ARPS board
Pump inhibition	/APSTOP	To PBP/Infusion pump, Replacement pump, Dialysate pump, Effluent pump and Blood pump
Power enable for Blood pump	ENABLEMOT	To Blood pump (this signal is in fact connected to the Blood Pump Relay board and disconnects the pump from the supply when e.g. manual end-of-treatment is used)
Blood pump speed supervision	BP_ENCODER	From Blood pump
Syringe pump supervision	SPEED_OUT, DIR_OUT	From Syringe pump
ABD (Air Bubble Detection) management	ABD_TEST, UB_TEST (not used), ABD_Alm_Rst_A, ABD_Alm_Rst_B and ABDA_ALM	PIB board
ABD trouble detection	TRBL_ALM	From PIB board
Visual Alarm	LAMP_POWER (= +5Vprot), RED_LAMP, YELLOW_LAMP, GREEN_LAMP	To Alarm light module
Audible Alarm	COIL_OUT, GND	To alarm buzzer
Control system alarm control – currently not used	AUX_BUZZ_IN, GND-pull-down	From Carrier board
Power supply to Touch screen controller	+5Vd, GND	To touch screen controller
Power supply to CD-ROM player	+5Vd, GND	To CD-ROM player
Power supply to hour meter	+5Vprot, GND	To hour meter
Power supply to fan	+12Vout, FAN_ENCODER, GND	To fan (3 signals; +12V, GND and FAN_ENCODER)
I2C bus	+5Vd, I2C_SDA, I2C_SCL, GND	Carrier board and PIB board
Back-up battery test	TEST_BAT	To PSU
Battery test status	OUT_TBAT	From PSU

ARPS board

The ARPS (Automatic Repositioning System) board has the following main functions:

- Monitors the pressure values from Access pressure sensor, Return pressure sensor, Filter pressure sensor, Effluent pressure sensor and Auxiliary pressure sensor
- Monitors the internal ARPS pump line pressure sensor
- Controls the valves between the ARPS pump and the pressure sensors for access pressure, return pressure, filter pressure, effluent pressure and auxiliary pressure
- Controls the ARPS pump to adjust pressure sensor membrane positions and for creating pressure levels for taring and testing the pressure sensors
- Handles the increase or decrease of the fluid level in the deaeration chamber
- Provides voltage references for pressure sensor bridges and internal ADC; +10V for sensor bridges (ARPS_VDD), +5Vref for ADC and +2.5V for pressure sensor neutral position reference

Description	Signals	Interfacing board(s)/module(s)
Access pressure sensor voltage reference and measurement signal	ARPS_VDD, AP_High_bridge, AP_Low_bridge, GND, Shield	Access pressure sensor
Return pressure sensor voltage reference and measurement signal	ARPS_VDD, VP_High_bridge, VP_Low_bridge, GND, Shield	Return pressure sensor
Filter pressure sensor voltage reference and measurement signal	ARPS_VDD, FP_High_bridge, FP_Low_bridge, GND, Shield	Filter pressure sensor
Effluent pressure sensor voltage reference and measurement signal	ARPS_VDD, EP_High_bridge, EP_Low_bridge, GND, Shield	Effluent pressure sensor
Auxiliary pressure sensor voltage reference and measurement signal	ARPS_VDD, AuxP_High_bridge, AuxP_Low_bridge, GND, Shield	Auxiliary pressure sensor
ARPS pump line pressure sensor voltage reference and measurement signal	ARPS_VDD, ARPSP_High_bridge, ARPSP_Low_bridge, GND, Shield	ARPS pressure sensor
Control of Access pressure sensor valve	ARPS_VDD, AV_Open drain	To access pressure sensor valve
Control of Return pressure sensor valve	ARPS_VDD, VV_Open drain	To return pressure sensor valve
Control of Filter pressure sensor valve	ARPS_VDD, FV_Open drain	To filter pressure sensor valve
Control of Effluent pressure sensor valve	ARPS_VDD, EV_Open drain	To effluent pressure sensor valve
Control of Auxiliary pressure sensor valve	ARPS_VDD, AuxV_Open drain	To auxiliary pressure sensor valve
Control of ARPS pump	ARPS_VDD, 4 open drain H-bridge outputs for stepper motor coil	To ARPS pump
I2C bus	+5Vd, I2C_SDA, I2C_SCL, GND	PIB board and Effluent Scale

PIB board

The PIB board has the following main functions:

- Handles the air bubble detector
- Monitors the optical switch to detect that the blood line is present in air bubble detector
- Activates the venous clamp (through I2C)
- Monitors the venous clamp position
- Monitors the blood detector (through I2C)
- Monitors the blood leak detector (through I2C)
- Controls and monitors the position of pinch valve for dialysate line
- Controls and monitors the position of pinch valve for infusion line

Description	**Signals**	**Interfacing board(s)/module(s)**
Monitoring of air bubble detector	UABD_RCV, UABD_TRANS-MIT, REF_BIG, REF_MICRO, GND	ABD (Air Bubble Detector) assembly
Monitoring of blood detector	PTSR_K, PTSR_A, PTST_A, PTST_K	ABD (Air Bubble Detector) assembly
Monitoring of blood line present detector	+5VP, UABD_LS, LSS2, GND	ABD (Air Bubble Detector) assembly
Monitoring of blood leak	BLDT-A, BLDT-K, BLDR-A, BLDR-K, GND	Blood leak detector board
Control of Dialysate line pinch valve	CL_MOT2_OUT1, CL_MOT2_OUT2	To dialysate line pinch valve
Control of Infusion line pinch valve	CL_MOT1_OUT1, CL_MOT1_OUT2	To infusion line pinch valve
Monitoring of Dialysate line and Infusion line pinch valves position	+5VP, PV_OPT_COM, S1_MOT1, S2_MOT1, S3_MOT1, S1_MOT2, S2_MOT2, S3_MOT2, GND	From dialysate line pinch valve and Infusion line pinch valve position detector board
Control of venous clamp	CLAMP_CMD, +24Vm	To venous clamp
Monitoring of venous clamp	+5VP, VCP, LVCS, GND	Venous clamp detector board
I2C bus	+5Vd, I2C_SDA, I2C_SCL, GND	Protective CPU board and ARPS board

Alarm light module

The Alarm light board consists of two rows of LEDs on three different PCBs mounted in a triangle to provide 360° visibility. One of the LED rows displays red and yellow light. The other displays green light. The alarm light is controlled by the Protective CPU.

Description	Signals	Interfacing board(s)/module(s)
Visual Alarm	LAMP_POWER (= +5Vprot), RED_LAMP, YELLOW_LAMP, GREEN_LAMP	To Protective CPU board

LVDS interface board

Note: LVDS transmitter board is only present on older Prismaflex control units. See Service Newsletter for specific Prismaflex control unit numbers.

The LVDS interface board converts the parallel digital LCD display signals from the Control CPU into serial LVDS signals.

Description	Signals	Interfacing board(s)/module(s)
Parallel LCD interface	24 bit color, VSYNC, HSYNC, SHFCLK, DE, ENAVDD, +12Vout, +5Vd and GND	Control CPU board
LVDS to TFT screen	4 shielded TP LVDS signals, TFT_VCC, +5Vd and GND	TFT screen

External RS232 board

The external RS232 board provides an isolated serial communications port for external equipment.

Description	Signals	Interfacing board(s)/module(s)
Power and communication for external RS232 interface	Rx, Tx, RTS, CTS, +5Vd, GND	Carrier board

External Ethernet board

The external Ethernet board provides an isolated Ethernet port for external equipment.

Description	Signals	Interfacing board(s)/module(s)
External Ethernet interface signals	IRX–, IRX+ ITX– and ITX+	Control CPU board

External Remote Alarm Connector

The external Remote Alarm interface provides a summary relay interface to a remote alarm device. The summary relay closes the circuit when Prismaflex control unit issues a Warning alarm, a Malfunction alarm or an Advisory alarm. Whenever the issued alarm is overridden (or in some cases when softkey *CONTINUE* is pressed), the relay opens the remote alarm circuit. The relay circuit must be powered by the remote alarm device.

Description	Signals	Interfacing board(s)/module(s)
Open / Closed relay circuit for connection to a Remote Alarm device. Relay rating: 26VAC @ 1A	Open /closed relay circuit pin 1 and 4	Remote Alarm Relay Board

WARNING

The clinic/user is solely responsible for connecting a remote alarm to the Prismaflex control unit and for verifying its function. If a remote alarm is used, the operator is responsible for periodically checking on the patient in person.

WARNING

Fluid pumps

The Dialysate pump, Effluent pump, Replacement pump and additional PBP (Pre-blood pump) are all slave pumps with individual electronics boards. These pumps are controlled through commands passed through the I2C communication bus. Each pump has an unique I2C address and this address is configured using jumpers on the intergrated circuit board. The fluid pumps are responsible to control and monitor the pump rotation direction and speed according to the commanded value.

Description	Signals	Interfacing board(s)/module(s)
Power supply input	+24Vm, +5Vd, GND	From PSU

Blood pump

The Blood pump is a slave pump with an individual electronics board. The pump is controlled through commands passed through the I2C communication bus. The Blood pump controls the pump rotation direction and speed according to the commanded value.

Description	Signals	Interfacing board(s)/module(s)
Power supply input	+24Vm, +5Vd, GND	PSU
Motor stop and supervision	BP_ENCODER, /APSTOP, ENABLEMOT	Protective CPU board
Monitoring of speed and direction	+5Vd, Position_1, Position_2, GND	Hall sensors mounted on motor
I2C bus	+5Vd, I2C_SDA, I2C_SCL, GND	Replacement pump

Syringe pump

Depending on the selected anticoagulation method, the syringe pump is used for infusing anticoagulant or calcium solutions. The Syringe pump controls and monitors the infusion to the line set by moving its actuator to push the piston of a syringe, when commanded by the Control CPU (through I2C). There are built-in detection of end-of-stroke and overload and the presence of a syringe can be detected.
The movement of the actuator, during installation of syringe, can be performed manually through the two hardkeys on the side of the Prismaflex control unit or the softkeys on the screen.

Description	**Signals**	**Interfacing board(s)/module(s)**
Power supply input	+24Vm, +5Vprot, GND	PSU
Motor stop and supervision	SPEED_OUT, DIR_OUT	Protective CPU board
I2C bus	+5Vd, I2C_SDA, I2C_SCL, GND	Replacement scale and PBP / Infusion pump

Loader

The Loader handles the mounting of an attached line-set by pulling it in position so that the fluid pumps and Blood pump can auto route the pump segments into the slave pump runways.

Description	**Signals**	**Interfacing board(s)/module(s)**
Power supply input	+24Vm, +5Vd, GND	PSU
I2C bus	+5Vd, I2C_SDA, I2C_SCL, GND	Effluent / infusion pump and Dialysate / infusion pump

Scales

The scales provides a reading of weight of the different fluid bags to two different channels for the Control and Protective systems. Also reporting to Protective that the bag holder is properly inserted into the scale. All information is passed through I2C.

Description	**Signals**	**Interfacing board(s)/module(s)**
Power supply input	+12Vout, –5Va and GND	PSU
I2C bus	+5Vd, I2C_SDA, I2C_SCL, GND	Effluent scale: ARPS board and PBP/Infusion scale PBP/Infusion scale: Effluent scale and Dialysate scale Dialysate scale: PBP/Infusion scale and Replacement scale Replacement scale: Dialysate scale and Syringe pump

ABD assembly

The ABD has the following main functions:

- Detects air in the blood returned to the patient
- Detects blood in the return line

Signals

This section describes the signals between the modules inside Prismaflex control unit.

Signal name	**Description**	**From**	**To**
EN_24Vm	TTL square wave > 3 Hz used as watchdog to enable the +24Vm voltage.	Protective	PSU
UB_TEST	Logic TTL signal, Protective activates this signal (active low) 4 times each second for a duration of 8ms to test the air bubble detector. The air bubble alarm must then be activated within 5ms.	Protective	PIB
ABDA_ALM	Logic TTL signal, PIB sends this signal to protective when a macrobubble has been detected.	PIB	Protective
TRBL_ALM	Logic TTL signal, PIB sends this signal to protective when trouble has been detected, which means that the AGC has not been able to control the amplitude of the received signal.	PIB	Protective
ABD_Alm_Rst_A	Logical TTL signal to clock the flip-flop for air bubble detector alarm. Not active status is high.	Protective	PIB
ABD_Alm_Rst_B	Logical TTL signal for clearing data of the flip-flop for air bubble detector alarm. Not active status is high.	Protective	PIB
/APSTOP	Logic TTL signal to enable the driver stage of the pumps P1, P2, P3, P4 and BLD.	Protective	P1, P2, P3, P4 and BLD
Brightness control	Analog voltage (0 – 3.75V) to control brightness of backlight to TFT.	Carrier	Inverter
Refhigh	3.75V	Carrier	Inverter
STEPDW	Logic TTL signal to enable inverter for backlight to TFT.	Carrier	Inverter
DIR_OUT	Logic TTL signal to indicate Syringe pump direction. (Low = CW, up. High = CCW, down)	Syringe pump	Protective
SPEED_OUT	TTL square wave from magnetic encoder to verify the speed of the Syringe pump. 16 pulses for each mm of vertical movement.	Syringe pump	Protective
ENABLE_12	Enable signal from protective to activate the 12V power on the ARPS board used for the ARPS pump. It is a square wave TTL level of 20 Hz frequency which stimulates the watch-dog on the ARPS board.	Protective	ARPS

Signal name	Description	From	To
ARPS_VDD	+10V reference voltage for pressure sensor bridges.	ARPS	Protective
ARPS_AVCC	+5V reference voltage for pressure sensor ADC.	ARPS	Protective
ARPS_VREF	+2.5V reference voltage for neutral position reference for pressure sensors.	ARPS	Protective
COIL_OUT	Analog sinusoidal signal 1 kHz, 1.5 kHz or 2.5 kHz sent to the alarm speaker (buzzer). The maximum amplitude can be 2Vpp with offset 0V.	Protective	Speaker
AUX_BUZZ_IN	Digital square wave signal TTL level of frequency 1 kHz, 1.5 kHz or 2.5 kHz sent to the from Carrier to Protective.	Carrier	Protective
POWER_FAIL	Logic TTL signal. Low indicates that no power from the supply line has been detected.	PSU	Carrier and Protective (through Carrier)
POWER_RESET	Logic TTL signal. Low indicates the PSU is in reset condition.	PSU	Carrier and Protective (through Carrier)
FAN_ENCODER	Open collector pulse signal from cooling Fan pull-up on Protective board used to read the speed of the Fan.	Cooling Fan	Protective
BAR-CODE_TRIG	Logic signal TTL level; Low level indicates that barcode reader is active.	Carrier	Bar-code reader
TFT_VCC	A delayed +5V power to the TFT. The delay is controlled by a signal from Control CPU; ENAVDD.	LVDS_Tx board	TFT
ENAVDD	Digital signal TTL level controlling the output power to the TFT.	Control CPU	LVDS_Tx board
BP_ENCODER	Digital signal TTL level pulses indication of Blood pump motor speed. (gear box 30:1)	Blood pump	Protective
ENABLEMOT	Digital signal open drain to connect the Blood pump motor to the driver H-bridge. Low level connects the motor to the bridge. Relay coil at motor is used as pull-up.	Protective	Blood pump
TEST_BAT	Digital open drain signal to activate battery test by connecting a resistive load to the back-up battery and monitoring the resulting voltage across the battery. Low level activates the test.	Protective	PSU
OUT_TBAT	Digital TTL status signal for back-up battery test. Low level during the test indicates that the battery is charged. High level indicates low battery voltage.	PSU	Protective

Chapter 4

Function Check

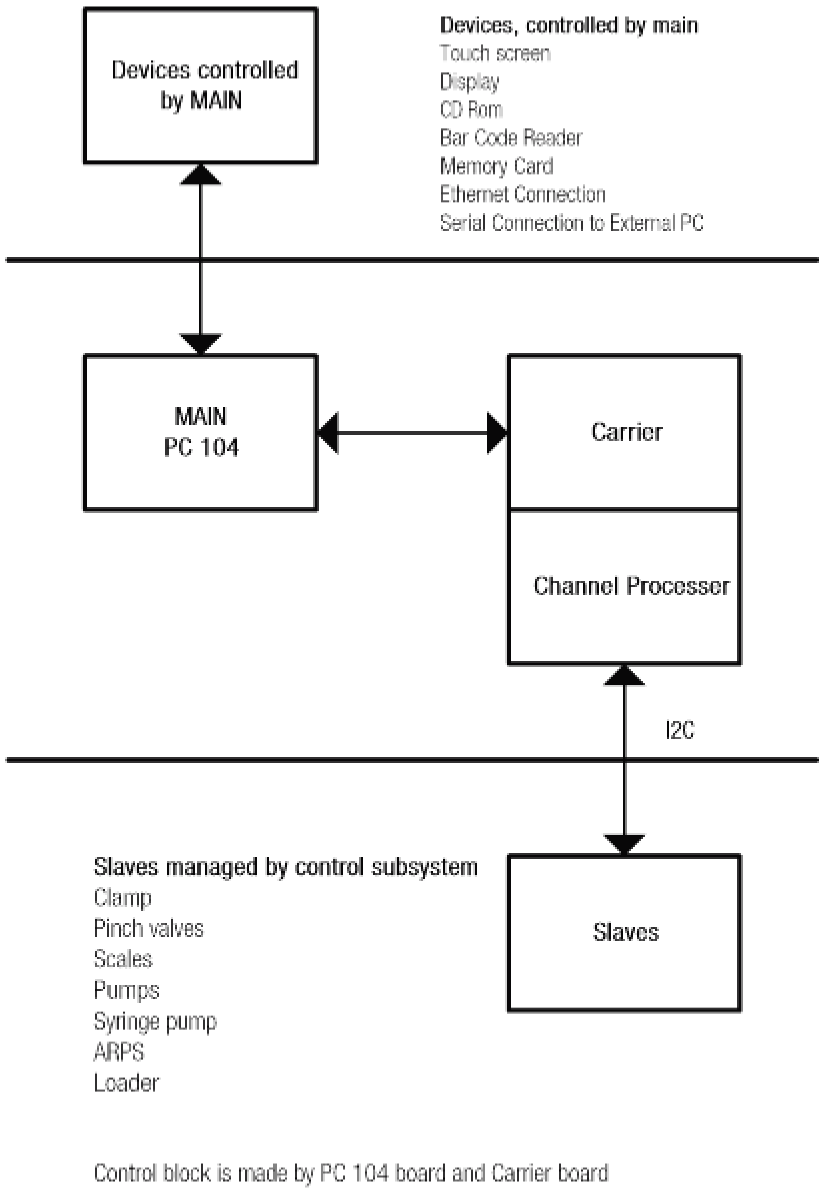
Contents

About this Chapter 4:2
Main-controlled Components 4:3
Self–tests 4:4
Operating System Initialization 4:4
Initialization Test 4:5
Prime Self-test 4:8
Pre-Prime 4:8
Post-Prime 4:13
Periodic Self-test 4:21
Alarm Monitoring During the Periodic Self-Test 4:23
Technical Screens 4:24
First Technical Screen 4:24
Second Technical Screen 4:29
Third Technical Screen 4:32
Fourth Technical Screen 4:35
Fifth Technical Screen 4:36
Sixth Technical Screen 4:37

About this Chapter

Prismaflex control unit software continually monitors the operation of the Prismaflex control unit and the Prismaflex disposable set. To ensure the functionality of the Prismaflex control unit throughout the whole treatment several tests are performed. These tests can be divided into four sets of self-test. This chapter describes the sequences.

Main-controlled Components



Structure of commands and communication of the Prismaflex control unit

Self–tests

The Prismaflex software continually monitors the operation of the Prismaflex control unit and performs diagnostic self tests to ensure that the operation is within specifications. Each self-test consists of a series of subtests done in a sequential order. The self-tests can be separated into four different categories:

- Operating System Initialization
- Initialization Tests
- Prime Self-Tests
- Periodic Self-Tests

Operating System Initialization

The Operating System Initialization test starts when the Prismaflex control unit is switched on, and consists of two subtests:

1. Basic Input Output Software (BIOS)
2. VxWorks Operating System

1. BIOS Software

When the Prismaflex control unit is switched on, the Basic Input Output Software (BIOS) of the PC104 is executed. The BIOS executes a memory test on the PC104 board RAM and its ability to communicate with hardware components.
During the initialization the boot file (bootrom.sys) is read and executed from the first sector on the PC104's compact flash.

2. VxWorks Operating System

The system boots each of the boards in the Prismaflex control unit.
The following boards are initialized:

- Carrier Board
- Protective Board
- PIB Board (Peripheral Interface)
- ARPS Board (Automatic Repositioning System)

When the boot file is finished being read the VxWorks application program is initialized. VxWorks is a real time multi-tasking operating system used to run the application program of the Prismaflex control unit.
The *VxWorks* screen appears and the application programs begin to load from the PC104's compact flash.

Initialization Test

The initialization test checks that the Control and Protective microprocessors and memory are operating properly. When the initialization test begins, the *Logo* screen appears on the Prismaflex control unit display, the non-mutable buzzer sounds, and the status lights are lit during the test. After the initialization test completes, the Prismaflex control unit enters Setup mode. The initialization test consists of seven subtests, of which six are automatic and one is up to the service technician to verify:

1. Processor Flag Check
2. Write-to and Read-from RAM
3. Calculation of Cyclical Redundancy Check (CRCs)
4. Communication between Microprocessors
5. Audio & Visual Alarm Activation
6. Information Structures Stored in Main Compact Flash and Protective CPU Eprom
7. Start-up Conditions

1. Processor Flag Check

The processor verifies that all condition flags can be set.
This test accesses the protective system, microprocessor registers and branch instructions. The test verifies that the protective slave can receive output data instructions.

2. Write-to and Read-from RAM

Whatever is read from the RAM must match what is written.
The protective system RAM is verified in a two-step process. First the protective system writes predefined data to a fixed address of the RAM. Secondly the protective system tries to read the data from the fixed address of the RAM. The protective system then compares the written and read data and verifies that the information is the same. This verification is performed on the Carrier (channel processor) and Protective systems.

3. Calculation of Cyclical Redundancy Check (CRCs)

The calculations must match the CRCs stored in ROM. If the calculations are correct, the ROM is not corrupted.
Cyclical Redundancy Check (CRC) is a process which verifies that program data is not corrupt. By summing all the bits of the information in a software program a CRC can be calculated and represented as a 16–bit number in hex format.
During the initialization of the application programs CRC verifications are performed on the slave boards to ensure that the program data has not been corrupted.

The following software programs located on the slaves are CRC checked during initialization (both boot loader and application software are checked):

- Carrier Slave (software for channel processor)
- Protective Slave
- PIB Slave
- ARPS Slave
- Scales

The software of the Protective Task that was executed on PC104 is CRC checked by calculating the CRC of the PROTEC.OUT file and comparing it with the CRC written in the PROTEC.CRC file. Both files are located on the Compact Flash of the PC104 board.

4. Communication between Microprocessors

Both Control and Protective microprocessors must write and read data from the I2C bus. This process verifies that both systems can communicate with all hardware connected to the I2C bus.

5. Audio & Visual Alarm Activation

The Protective system activates the Green, Yellow and Red LED alternately. The buzzer is activated during this process. The Prismaflex control unit has no internal monitoring for this process so it is the responsibility of the operator to verify the correct operation of this process.

6. Information Structures Stored in Main Compact Flash and Protective CPU Eprom

Two verifications are performed here; (a) Checksum Verification (b) Range Verification

a. Checksum Comparison
   Checksum of each structure is compared to the software-calculated checksum for that structure. Information structures stored on the PC 104 compact flash and the Protective system processor are verified for errors.
   A checksum of the following information structures are performed:

   - SDB (System Data Base)
   - Custom.ini (stores all the different settings made by customer)
   - Library.ini (stores all the default settings)

b. Range Check
   Information structures which contain minimum and maximum setting values are range checked to ensure the range is valid.

7. Start-up Conditions

The Prismaflex control unit displays information about next preventive maintenance. Messages that can appear is:

- "`Overdue`" if PM not done within time
- "`Due in dd day(s)`" if calendar time is nearest PM
- "`Due in hhh hour(s)`" if operation time is nearest

The Prismaflex control unit performs a test to determine if a Battery backup is installed or not. If the systems runs on a 12V battery system a periodic battery check executes. If battery is below specific battery limit, the `ADVISORY: Memory backup alarm` is displayed with the option to *OVERRIDE*.

The way that the Prismaflex control unit was turned off, determines how the Prismaflex control unit will start. There are three different screens that can be displayed:

- The regular Prismaflex System screen
- `Query` screen
- Alarm screen
  If an alarm occurs,see Alarms and Troubleshooting chapter for details on how to remedy the alarm.

Prime Self-test

The prime self-test consists of two phases of subtests:

- Pre-prime
- Post-prime

The pre-prime phase starts when the softkey *NEW PATIENT* or *SAME PATIENT* is selected. The service technician manually starts the post-prime phase of testing by pressing the *PRIME + TEST* softkey in `Verify Setup` screen or the *PRIME TEST* softkey on the `Priming X of Y Cycles Complete` screen. During the testing process, if any subtest fails, an alarm occurs informing the service technician about the specific failure and provides instructions.

Note: A congruency check on the system database is performed before the Pre-Prime phase of the Prime Self-test.

Pre-Prime

The pre-prime phase includes ten subtests:

1. 24 V Battery Backup Test
2. Scale Zero Test
3. Pressure Zero Test
4. Line Presence Sensors of ABD and Return Line Clamp (Pre–Prime)
5. Scale Position Test
6. Pinch Valve Position Test
7. Effluent Line Check
8. Syringe Line Check
9. Positioning of Pinch Valves
10. Recognition Test
11. Syringe Pump

1. 24 V Battery-Up Test

Executes only when the Prismaflex control unit is equipped with 24V Battery Backup. The test is activated when the softkey *NEW PATIENT* is selected. The protective system checks the limit status of the voltage of the 24 V battery.

Alarm generated is;
ADVISORY: `Battery Exhausted`
Options:*OVERRIDE*

2. Scale Zero Test

The test is activated when the softkey *NEW PATIENT* or *SAME PATIENT* is selected. The protective system acquires the A/D conversion value for each scale from its scale board via the I2C bus. The A/D values are then converted to weight using the protective calibration data. The protective system verifies that the load on the Effluent, Replacement, Dialysate and PBP scales are reading between ±30 g. This test verifies that the protective scale calibration is valid for 0 grams weight.

Alarm generated is;
MALFUNCTION: `Scale Zero Test`
Option:*RETEST*

3. Pressure Zero Test

The test is activated when the softkey *NEW PATIENT* or *SAME PATIENT* is selected. The protective system acquires the A/D conversion value for each pressure reading from the ARPS via the I2C bus. The A/D values are then converted to pressure using the protective calibration data. The protective system verifies that the pressure on the Access, Effluent, Filter and Return pressure sensors are reading ±15 mmHg. This test verifies that there is no external pressure on any of the sensors and that the protective pressure calibration is valid for atmospheric pressure.

Alarm generated is;
MALFUNCTION: `Pressure Zero Test`
Option: *RETEST*

4. Line Presence Sensors of ABD and Return Line Clamp

When the *NEW PATIENT* softkey is selected the Protective system checks the status of the line presence switch in the ABD. The micro switch must indicate that no line is present in the ABD. If a line is present an alarm message will trigger.
The test occurs both before and after a set is loaded. Do not insert the return line into the air detector before the set is loaded. After loading, the return line should be present in the detector.

Alarms generated are
MALFUNCTION: `Line in Air Detector`
Options:*RETEST, OVERRIDE*

When the *NEW PATIENT* softkey is selected the Protective system checks the status of the line presence switch the Return line clamp. The micro switch must indicate that no line is present in the Return line clamp. If a line is present an alarm message will trigger. The test occurs both before and after a set is loaded. Do not insert the return line into the clamp before the set is loaded. After loading, the return line should be present in the clamp.

Alarms generated are;
MALFUNCTION: `Line in Clamp`
Options:*RETEST, OVERRIDE*

5. Scale Position Test

After the selection of the Therapy mode by the operator the protective system monitors that the associated scale position sensors detect movement. The sensors on the scales involved in the selected therapy must change from closed to open. Then they must detect a change from open to closed (solution bag loaded). Then the protective system must detect a weight of higher than 100 grams on the scale. If this is performed before the *PRIME* button is pressed, then the test passes.

Alarms generated are;
WARNING: `Bag Volume Incorrect`
Options:*KEEP BAG, CONTINUE*
WARNING: Effluent Bag Incorrect
Options:*MODIFY BAG, CONTINUE*
MALFUNCTION: `Scale Sensor`
Options: *RETEST, OVERRIDE*

6. Pinch Valve Position Test

When pressing *LOAD* softkey, control system via the PIB board will command the dialysate and replacement pinch valves to move to neutral position. The protective system will then acquire position signals from the PIB board via the I2C bus and monitor that the pinch valves are in Neutral position.

Alarms generated are;
WARNING:`Loading Error`
Due To: Wrong pinch valve position when pressing *LOAD*
Options:*RETEST*

7. Effluent Line Check

Protective system will check that effluent line is installed in the blood leak detector.

Alarms generated are;
WARNING: `Effluent Line Not in BLD`
Due To: Effluent line not installed in BLD when pressing *LOAD*
Options: *RETEST, DISCONNECT*

8. Syringe Line Check

During the priming of the calcium line, hence the user has chosen Citrate – Calcium, Prismaflex syringe pump, a test will be performed, checking that the correct line is used and that the dedicated calcium line is not clamped. If any of these tests fail, one of the following alarms will be triggered.

Alarms generated are;
WARNING:`Ca Line Not Connected`
Options: *CONTINUE, CHANGE SYR/LINE*
WARNING:`Calcium Line Clamped`
Options: *CONTINUE, CHANGE SYR/LINE*

9. Positioning of Pinch Valves

After the set has been loaded the control system via the PIB board will command the dialysate and replacement pinch valves to move through all of their positions. The protective system will then acquire position

signals from the PIB board via the I2C bus and monitor that the pinch valves are able to actuate through each of the three positions. The pinch valves valve positions are detected with their associated optical sensors.

Upper Pinch Valve: The protective system commands the upper (dialysate) pinch valve into the dialysate position, and its position is verified by the position sensors.
The pinch valve is then commanded into the neutral position and is again verified by the position sensors.
Finally the pinch valve is commanded into the replacement 2 position and verified by the position sensors.

Lower Pinch Valve: The protective system commands the lower (pre/post) pinch valve into the pre position, and its position is verified by the position sensors.
The pinch valve is then commanded into the neutral position and is again verified by the position sensors.
Finally the pinch valve is commanded into the post position and is verified by the position sensors.

Alarms generated are;
MALFUNCTION:`Prime Self-Test`
Code: 21
Due To: Upper pinch valve
MALFUNCTION:`Prime Self-Test`
Code: 22
Due To: Lower pinch valve
MALFUNCTION:`Prime Self-Test`
Code: 23
Due To: Upper and lower pinch valve
Options: *RETEST, DISCONNECT, NEW SET*

10. Recognition Test
The venous clamp closes. The upper pinch valve closes the Dialysate line. The Prismaflex control unit measures for effluent, filter and return reference pressures. The Dialysate pump runs for 4 s. The Prismaflex control unit looks for pressure differences. In case of unexpected change, “Warning: Set-up error” is triggered.
CRRT: The Prismaflex control unit looks for a pressure change of more than 5 mmHg.

Alarms generated are;
WARNING:`Set-up error`
Options: *UNLOAD, RETEST*

TPE, HP: As there is no dialysate line in this therapy, the Prismaflex control unit looks for a pressure change of less than 5 mmHg.
The bar code is read at loading. If the identified bar code mode is different than the selected one (TPE set for CRRT set for example), then the alarm “Warning: Wrong set loaded” is triggered.

Alarms generated are;
WARNING:`Wrong set loaded`
Option: *UNLOAD*

11. Syringe Pump

During the `Syringe Installation` the pump direction and speed function is verified. The operator is prompted to activate the syringe pump in the downward direction (by either pressing the auto down or by pressing the hard-keys with a downwards arrow). The protective system then acquires the encoder signals directly from the syringe pump board and verifies the pump direction and rate. The operator is prompted to activate the syringe pump in the upward direction. The protective system then acquires the encoder signals directly from the syringe pump board and verifies the pump direction and rate.
This must be completed within 6 minutes or the alarm `Malfunction: Syringe Pump Hardware` is generated.

Alarm generated is;
MALFUNCTION:`Prime Self-Test`
Code: 28
Due to: Syringe Pump Hardware
Options:*RETEST, DISCONNECT*

Post-Prime

Before Post prime tests are performed, a wrong set selected test is done in case of bar code reading has failed: Low Flow (LF) and High Flow (HF) set check. Mass variation (Δm) on each of the Effluent, PBP, Dialysate and Replacement scale records are used to check for LF set use instead of HF set, and vice versa. If bar code reading has previously failed and the mass variation test fails, the alarm "Warning: Wrong Set Selected" is triggered.

The Post-Prime tests are performed once the priming of the set occurs and the service technician has pressed the *PRIME TEST* softkey on the *Priming X of X Cycles Complete* screen.

The Post-Prime phase includes eleven subtests:

1. Line Presence Sensors of ABD and Return Line Clamp (Post-loading)
2. BLD Normalization
3. BLD Test
4. +12 V ARPS Pump
5. Air/Pump Security (ABD)
6. Pump Occlusivity Test
7. Return Pressure Sensor
8. +24 V and Return Clamp
9. Pressure Pods Reposition
10. TMPa Calibration (only performed in TPE)
11. Remote Alarm Test

1. Line Presence Sensors of ABD and Return Line Clamp (Post-loading)

When the set has been loaded the protective system checks the status of the line presence switch in both the ABD and the Return line clamp. The micro switches must indicate that a line is present on both associated micro switch sensors.

Alarms generated are;
MALFUNCTION:`No Line in Air Detector`
MALFUNCTION:`No Line in Clamp`
Options:*RETEST, OVERRIDE, DISCONNECT*

Note: If *OVERRIDE* is selected the Prismaflex control unit is able to continue, but will display a Caution alarm ”Yellow alarm light” throughout the treatment. An alarm message in the `Examine alarms` screen will also be present.

2. BLD Normalization

Immediately after selecting the *PRIME TEST* softkey the Protective system requests the PIB board to normalize the BLD.
The PIB adjusts the level of the BLD's transmitter IR LED between transmitter PWM (Pulse Width Modulation) levels of 0% (transmitter OFF) and 100% (transmitter full ON). It uses the bisection method until the BLD IR receiver has reached a value of 43500 ±1280.
Then the PIB responds to the protective system the Normalization has completed. The protective system checks that the transmitter PWM level is lower than 45%, that the receiver value remains within 43500 ±1500 and that the receiver value is below 3000 when the transmitter is switched OFF.
If the PIB has not responded to the protective system that the normalization has completed within 30 seconds or the values of the receiver and transmitter PWM are determined to be out of range by the protective system the test has failed. The protective system can request the PIB to perform the Normalization three times before issuing an alarm.

Alarm generated is;
MALFUNCTION:`Prime Self-Test`
Code: 17
Due To: Blood Leak Detector Normalization Time-out, Normalization value 0
Options: *RETEST, DISCONNECT, NEW SET, REPRIME*

3. BLD Test

Two seconds after a successful BLD normalization the BLD test is performed. The transmitter PWM is lowered to a level simulating a blood leak. The receiver value must be reduced to a value below 15000 within 5 seconds, which is equal to the detection of a blood leak.

Alarm generated is;
MALFUNCTION:`Prime Self-Test`
Code: 18
Due To: Blood Leak Detector Threshold error
Options:*RETEST, DISCONNECT, NEW SET, REPRIME*

4. +12 V ARPS Pump

The Protective circuit board disables the 12 V relay that powers the Automatic Repositioning system motor. Protective circuit board then checks to see if the relay is disabled, and finally, re-enables the relay. The protective system requests the control system to start turning the ARPS air pump. The protective system verifies that there is no leakage in the ARPS by looking for pressure changes in the ARPS. The protective system then disables the 12 V relay and checks that ARPS pump has stopped by monitoring the ARPS pressure and detects that there is no change. Finally the protective system re-enables the 12 V relay and checks that the ARPS pressure sensor value changes.

Alarm generated is;
MALFUNCTION:`Prime Self-Test`
Code: 24
Due To: 24 Volt / 12 Volt
Options: *RETEST, DISCONNECT*

5. Air/Pump Security (ABD)

Test verifies that the Control CCA activates a “safe state” wherein all pumps are stopped and the Return clamp is closed when a simulated air bubble is detected. The protective system commands the control system to start the Blood pump and the four fluid pumps only when the blood line in the Air Bubble Detector is filled with fluid.
An ABD alarm is simulated by reducing the ABD's transmitter power to a level causing the receiver to detect an Air bubble.
The protective system must see that the:

- Air in blood hardware alarm signal is activated
- Blood pump stop hardware command is activated
- All the pumps have really stopped

The protective system then sends the commands START BP PUMP and START FLUID PUMPS to the control system; all pumps must start.
The protective system then sends the commands STOP FLUID PUMPS to the control system and checks that each fluid pump remain stopped while the Blood pump is running.
The protective system then sends again the commands START BP PUMP and START FLUID PUMPS to the control system and checks that each pump run again.
The protective system then sends again the commands STOP BP PUMP and STOP FLUID PUMPS to the control system and checks that each pump remain stopped.
The protective system clears the ABD alarm signal.
The protective system checks that the trouble signal ABD has been activated by the receiver hardware circuitry when the ABD transmitter is first switched ON.

Alarm generated is;
MALFUNCTION:`Prime Self-Test`
Code: 19
Due To: Air/Pump Security Test
Options:*RETEST, DISCONNECT*

6. Pump Occlusivity Test

Tests whether the rollers of each peristaltic pump can completely occlude the tubing within the pump raceway and for external leakage in the Prismaflex disposable set (damaged component or setup error). The protective system commands the control to stop all the pumps and close the return line clamp. The protective system then commands the blood pump to start turning until the return pressure reach a specific pressure. The pressure is depending on the selected disposable set.

While the blood pump is turning, the protective system counts the number of rotations required to achieve this pressure using the encoder. The number of rotations must not be greater than a specific value dependent on the selected disposable set.

The protective system reads the values of the filter, effluent and return pressure sensors.

After waiting an additional 10 seconds the protective system again reads the pressure values and compares them with the initial recorded values.

Allowed pressure drop depends on selected disposable set.

Alarm generated is;
MALFUNCTION:`Prime Self-Test`
Code: 20
Due To: Pump Occlusivity Test
Options:*RETEST, DISCONNECT, NEW SET, REPRIME*

7. Return Pressure Sensor

Immediately after the Occlusivity test the return pressure will normally be greater than 250 mmHg. The protective system commands the control system to run the ARPS pump until the ARPS pressure sensor is equal to that measured by Return pressure sensor.
The ARPS return valve is then opened and the pressure reading of the Return and ARPS pressure sensors must be within ±20 mmHg.

Alarm generated is;
MALFUNCTION:`Prime Self-Test`
Code: 16
Due To: Return Pressure Sensor
Options: *RETEST, DISCONNECT, NEW SET, REPRIME*

8. +24 V and Return Clamp

First the protective system commands the control system to close the Return clamp.
The protective system then disables the +24V relay in the Power supply and confirms that no +24V is supplied to the Prismaflex control unit.
Next the protective system re-enables the +24V relay, confirms that the +24V has been restored and checks that the Return clamp has remained closed during the above operations.
The protective system finally commands the clamp to open and checks that the position sensor, located in the clamp, has detected this correctly.

Alarms generated are;
MALFUNCTION:`Prime Self-Test`
Code: 24
Due To: 24 Volt / 12 Volt
MALFUNCTION:`Prime Self-Test`
Code: 25
Due To: Return Clamp Sensor
MALFUNCTION:`Prime Self-Test`
Code: 26
Due To: 24 Volt and Return Clamp Sensor
Options:*RETEST, DISCONNECT*

9. Pressure Pods Reposition

Access, Filter and Effluent pressure pod sensors

During this test the pressure pods are repositioned and the sensors are checked in the following sequence:

a. Effluent pressure sensor

b. Access pressure sensor

c. Filter pressure sensor

Repositioning using the First algorithm:

Effluent pressure pod/sensor: the initial pressure of the Effluent pressure sensor is measured and stored. The ARPS pump is then commanded to run until the ARPS pressure sensor is equal to the initial effluent pressure value. A verification of the Effluent pressure sensor is performed, it must be equal to the ARPS pressure sensor ±20 mmHg for at least 2 seconds. The ARPS pump is then commanded to run for a maximum of 3000 steps to decrease the Effluent pressure by 100 mmHg. After this the ARPS pump changes direction and re-introduces approximately 1 ml of air (about ½ the working range of the pod).

The effluent valve is closed and the repositioning sequence of the Access pressure pod/sensor is started.

Note: If during the repositioning sequence the effluent and ARPS pressure sensor values differ by more than 20 mmHg for longer than 5 sec. the valve closes and the verification/repositioning has failed. The repositioning of this pod/sensor is skipped and the protective system will start the repositioning on the next pod/sensor.

Access pressure pod/sensor: the initial pressure of the Access pressure sensor is measured and stored. The ARPS pump is then commanded to run until the ARPS pressure sensor is equal to the initial access pressure value.

A verification of the Access pressure sensor is performed it must be equal to the ARPS pressure sensor ±20 mmHg for at least 2 seconds.

The ARPS pump is then commanded to run for a maximum of 3000 steps to decrease the access pressure by 100 mmHg. After this the ARPS pump changes direction and re-introduces approximately 1 ml of air (about ½ the working range of the pod).

The access valve is then closed and the repositioning sequence of the Filter pressure pod/sensor is started.

Note: If during the repositioning sequence the access and ARPS pressure sensor values differ by more than 20 mmHg for longer than 5 sec. the valve closes and the verification/repositioning has failed. The repositioning of this pod/sensor is skipped and the protective system will start the repositioning on the next pod/sensor.

Filter pressure pod/sensor: the initial pressure of the Filter pressure sensor is measured and stored. The ARPS pump is then commanded to run until the ARPS pressure sensor is equal to the initial filter pressure value.

A verification of the Filter pressure sensor is performed; it must be equal to the ARPS pressure sensor ±20 mmHg for at least 2 seconds.

The ARPS pump is then commanded to run for a maximum of 3000 steps to increase the filter pressure by 100 mmHg. After this the ARPS pump changes direction and removes approximately 1 ml of air (about ½ the working range of the pod).

The Filter valve is then closed and the repositioning is complete.

Note: If during the repositioning sequence the filter and ARPS pressure sensor values differ by more than 20 mmHg for longer than 5 sec. the valve closes and the verification/repositioning has failed. The repositioning of this pod/sensor is skipped.

After the command to close the filter valve, the protective system waits 15 seconds before verifying that the Effluent, Access and Filter pressure sensors are within ±50 mmHg of their initial stored values.

For any pressure sensor that has failed the first repositioning sequence the protective system will command that a new repositioning sequence using the second repositioning algorithm be performed.

Repositioning using the Second algorithm:

The valve of the pressure sensor to be repositioned is opened.

For the negative pressure pods (Effluent and Access) the ARPS pump is commanded to run and remove air from the pod, pulling the pod membrane towards the Prismaflex control unit until the protective

system detects a pressure change greater 10 mmHg/sec for 3 seconds (it determines the plateau or end of travel for the pod membrane).

For the positive pod (Filter) the ARPS is commanded to pump air into the pod, pushing the pod membrane away from the Prismaflex control unit until the end of travel is detected.

The ARPS pump is then commanded by the protective system to run for a maximum of 3000 steps in the opposite direction pumping air into the pod (Effluent and Access) or removing air (Filter) while counting the number of steps of the stepper motor. When a pressure change is greater than 10 mmHg/sec, the end of travel of the pod membrane is again detected and the ARPS pump stops. The protective system then commands the ARPS pump to reverse direction again and run for half the number of steps previously counted between the pod membrane's ends of travel so placing the pod membrane in the middle of the pod before closing the valve.

Note: If during the repositioning sequence the access and ARPS pressure sensor values differ by more than 20 mmHg for longer than 5 sec. or the repositioning time-out has been reached >2 minutes the valve closes and the verification/repositioning has failed. The repositioning of this pod/sensor has failed. The protective system will start the repositioning on the next pod/sensor.

Note: The Access pod is repositioned with the same process as the Filter pod when the access pressure is positive.

Alarms generated are;
MALFUNCTION:`Prime Self-Test`
Code: 1
Due To: Pressure Pod/Sensor - Access
MALFUNCTION:`Prime Self-Test`
Code: 2
Due To: Pressure Pod/Sensor - Filter
MALFUNCTION:`Prime Self-Test`
Code: 3
Due To: Pressure Pod/Sensor - Access and Filter
MALFUNCTION:`Prime Self-Test`
Code: 4
Due To: Pressure Pod/Sensor - Effluent
MALFUNCTION:`Prime Self-Test`
Code: 5
Due To: Pressure Pod/Sensor - Access and Effluent
MALFUNCTION:`Prime Self-Test`
Code: 6
Due To: Pressure Pod/Sensor - Filter and Effluent
MALFUNCTION:`Prime Self-Test`
Code: 7
Due To: Pressure Pod/Sensor - Access, Filter and Effluent
Options: *RETEST, DISCONNECT, NEW TEST, REPRIME*

10. TMPa Calibration (only performed in TPE)

Using the Automatic Repositioning system, pressurizes the Filter, Effluent, and Return pressure sensors to various pressures, determines if the sensor characteristics are within 20 percent of each other, then returns the sensors to their initial pressures. Calculates initial TMPa in less than four minutes.

Alarm generated is:

MALFUNCTION:`Prime Self-Test`
Code: 27
Due To: TMPa calibration failed
Options: *RETEST, DISCONNECT, NEW TEST, REPRIME*

11. Remote Alarm Test

This test occurs when the `Prime Test Complete` screen is displayed. The protective system checks if it is able to generate a signal to a remote alarm device by simulating an alarm. The Prismaflex control unit will activate the red status light, and the remote alarm device.

Note: This test is performed even if there is not remote alarm connected to the Prismaflex control unit. The service technician is responsible to confirm if the remote alarm has been activated.

Periodic Self-test

A periodic self-test is conducted by the control unit during Run mode. A test is initiated at the following times:

- During patient treatment (Run mode): A periodic self-test is conducted every two hours. The first periodic self-test starts 10 minutes after Run mode is entered. If another alarm occurs at the scheduled start of a periodic self-test, the self-test may be delayed up to 15 seconds. Periodic self-test may be delayed 10 min by selecting the *DELAY TEST* softkey. When the user has initiated three delays of a due self-test the Advisory: Self-Test Overdue alarm occurs. Time schedule of the periodic self-test may also be automatically modified by the system according to next intervention schedule (bag change or syringe empty).

- If needed, an ongoing self-test can be interrupted by pressing the *STOP* softkey. Self-test is then restarted when pressing the *RESUME* softkey in the `Stop` screen.

- Following an operator's request (Run mode): A periodic self-test is conducted by pressing the *SELF-TEST* softkey from the `System Tools` screen.

Flow Rates can be read from the Flow settings field and Anticoagulation field of the `Status` screen. History information can be read from the `History` screen. A complete periodic self-test takes approximately 1 to 6 minutes. Once started, its progress is signalled to the operator through messages on the `Status` screen. Certain functions, including adjustments to treatment parameters, are unavailable during an ongoing test and the related softkeys are gray. Any treatment interruptions via the *STOP* softkey should be avoided during an ongoing test in order to allow for its swift and successful completion.

Note: The information icon "i" on the `Status` screen is lit with an orange color during self-test.

If any of the subtests fail, the ongoing run of the periodic self-test is terminated and a Malfunction: Self-test Failure alarm occurs. The alarm screen identifies the failed subtest and provides instructions for the operator.

The following four Periodic self-tests are performed:

1. Blood Leak Detector Test

2. +24 V and Return Clamp Test

3. Return Pressure Sensor Test

4. Pressure Pod Repositioning

1. Blood Leak Detector Test
As soon as the Periodic self-test has started the Protective system commands the PIB to start the BLD test. The transmitter PWM is lowered to a level simulating a blood leak. The receiver value must be reduced to a value below 15000 within 5 seconds, which is equal to the detection of a blood leak.

Alarm generated is;
MALFUNCTION:`Self-Test Failure`
Code: 18
Due To: Blood leak detector threshold error
Options: *RETEST, DISCONNECT*

2. +24 V and Return Clamp Test
First the protective system commands the control system to close the Return clamp. The protective system then disables the +24V relay in the Power supply and confirms that no +24V is supplied to the Prismaflex control unit. Next the protective system re-enables the +24V relay, confirms that the +24V has been restored and checks that the Return clamp has remained closed during the above operations. The protective system finally commands the clamp to open and checks that the position sensor in the clamp has detected this correctly.

Alarms generated are;
MALFUNCTION:`Self-Test Failure`
Code: 24
Due To: 24 Volt / 12 Volt
MALFUNCTION:`Self-Test Failure`
Code: 25
Due To: Return clamp sensor
MALFUNCTION:`Self-Test Failure`
Code: 26
Due To: 24 V and Return Clamp sensor
Options:*RETEST, DISCONNECT*

3. Return Pressure Sensor Test
The protective system commands the control system to run the ARPS pump until the ARPS pressure sensor is equal to that of the Return pressure sensor. The ARPS return valve is then opened. The pressure reading of the Return and ARPS pressure sensors must be within ±20 mmHg for each other.

Alarm generated is;
MALFUNCTION:`Self-Test Failure`
Code: 16
Due To: Return pressor sensor
Options:*RETEST, DISCONNECT, NEW SET, REPRIME*

4. Pressure Pod Repositioning
For repositioning of the pressure pods and the alarms generated, see Post-Prime, subtest 9.

Alarm Monitoring During the Periodic Self-Test

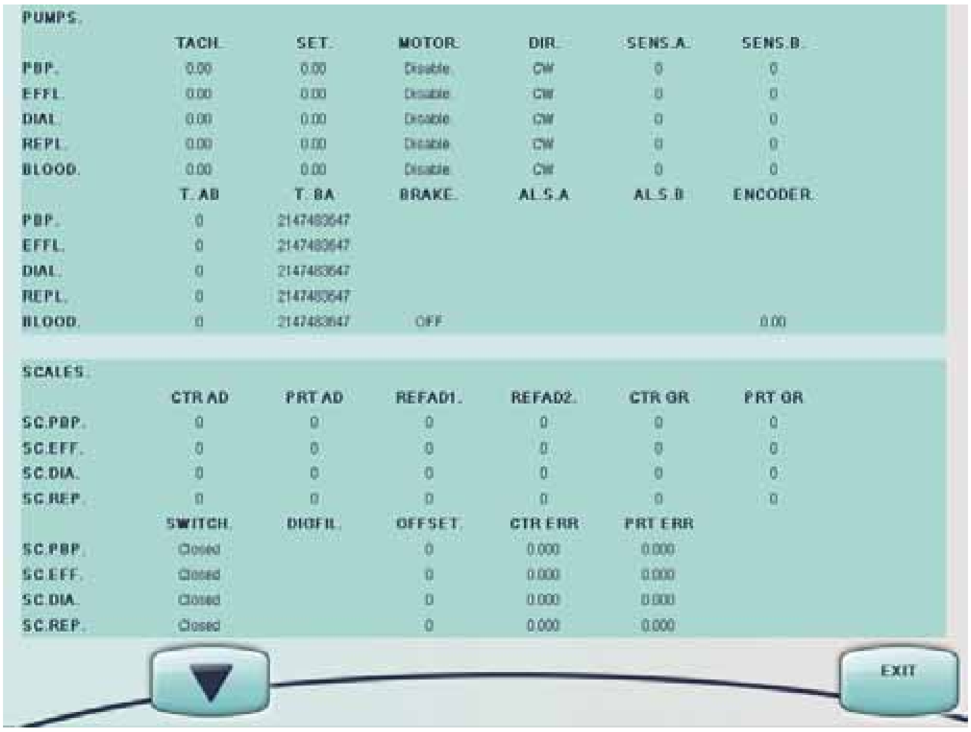
During the Periodic self-test some alarms are affected and they are managed in different ways depending on the subtest in progress. In the table below, the affected alarms are divided in Temporary limits and Disabled. Return pressure sensor is not affected during Periodic Self-test.

Subtest	**Alarm Name**	**Temporary Limit**	**Disabled**
Access Pressure Sensor	Access extremely negative (Monitored for negative pressure blood source only.)	100 mmHg below operator-set limit	
	Access extremely positive (Monitored for positive pressure blood source only.)	100 mmHg above operator-set limit	
	Check access		X
Filter Pressure Sensor	Filter extremely positive		Disabled during pressure sensor test
	Set disconnection		Disabled during filter repositioning
	Filter clotted		X
	Plasmafilter clotted (TPE)		X
	TMP excessive (CRRT)		X
	TMPa excessive (TPE)	100 mmHg above TMPa limit computed according to Blood Flow rate setting	
Effluent Pressure Sensor	Filter clotted		X
	Plasmafilter clotted (TPE)		X
	TMP excessive (CRRT)		X
	TMPa excessive (TPE)	100 mmHg above TMPa limit computed according to Blood Flow rate setting	

Technical Screens

The Technical Screens display technical data related to the current status of the control unit. Status information about pumps, scales, pressures, ABD, ARPS, Pinch Valves, Power Supply, Loader, bag tare data, installed software version and language package can be found. Also the barcode can be found in these screens. Press the date on the top right corner of any screen to access the Technical Screens. Use the *UP/DOWN ARROW* softkeys to navigate.

First Technical Screen



Parameter	**Description**
PBP. TACH.	Value, in rpm, of the PBP Pump speed read by the Protective side
EFFL. TACH.	Value, in rpm, of the Effluent Pump speed read by the Protective side
DIAL. TACH.	Value, in rpm, of the Dialysate Pump speed read by the Protective side
REPL.TACH.	Value, in rpm, of the Replacement Pump speed read by the Protective side
BLOOD.TACH.	Value, in rpm, of the Blood Pump speed read by Protective side
PBP. SET.	Value, in rpm, of the PBP Pump speed set by the Control side
EFFL. SET.	Value, in rpm, of the Effluent Pump speed set by the Control side
DIAL. SET.	Value, in rpm, of the Dialysate Pump speed set by the Control side
REPL.SET.	Value, in rpm, of the Replacement Pump speed set by the Control side
BLOOD.SET.	Value, in rpm, of the Blood Pump speed set by the Control side
PBP. MOTOR.	PBP Pump Motor status. Possible values displayed are: Enable/Disable

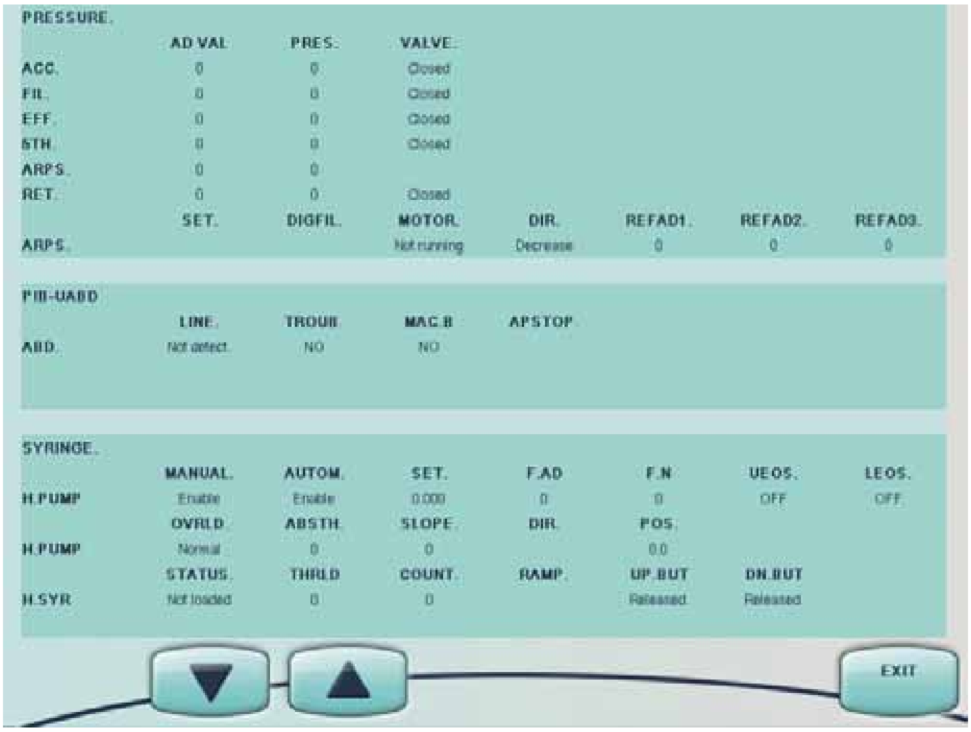
Parameter	Description
EFFL. MOTOR.	Effluent Pump Motor status. Possible values displayed are: Enable/Disable
DIAL. MOTOR.	Dialysate Pump Motor status. Possible values displayed are: Enable/Disable
REPL. MOTOR.	Replacement Pump Motor status. Possible values displayed are: Enable/Disable
BLOOD. MOTOR.	Blood Pump Motor status. Possible values displayed are: Enable/Disable
PBP. DIR.	PBP Pump running direction. Possible values displayed are: CW (clockwise)/CCW (counterclockwise)
EFFL. DIR.	Effluent Pump running direction. Possible values displayed are: CW (clockwise)/CCW (counterclockwise)
DIAL. DIR.	Dialysate Pump running direction. Possible values displayed are: CW (clockwise)/CCW (counterclockwise)
REPL. DIR.	Replacement Pump running direction. Possible values displayed are: CW (clockwise)/CCW (counterclockwise)
BLOOD. DIR.	Blood Pump running direction. Possible values displayed are: CW (clockwise)/CCW (counterclockwise)
PBP. SENS. A.	Number of pulses accumulated for the hall sensor A of the PBP Pump
EFFL. SENS. A.	Number of pulses accumulated for the hall sensor A of the Effluent Pump
DIAL. SENS. A.	Number of pulses accumulated for the hall sensor A of the Dialysate Pump
REPL. SENS. A.	Number of pulses accumulated for the hall sensor B of the Replacement Pump
BLOOD. SENS. A.	Number of pulses accumulated for the hall sensor B of the Blood Pump
PBP. SENS. B.	Delay between the time in which the magnet (on the PBP Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B
EFFL. SENS. B.	Delay between the time in which the magnet (on the Effluent Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B
DIAL. SENS. B.	Delay between the time in which the magnet (on the Dialysate Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B
REPL. SENS. B.	Delay between the time in which the magnet (on the Replacement Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B
BLOOD. SENS. B.	Delay between the time in which the magnet (on the Blood Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B

Parameter	Description
PBP. T. AB	Delay between the time in which the magnet (on the PBP Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B
EFFL. T. AB	Delay between the time in which the magnet (on the Effluent Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B
DIAL. T. AB	Delay between the time in which the magnet (on the Dialysate Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B
REPL. T. AB	Delay between the time in which the magnet (on the Replacement Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B
BLOOD. T. AB	Delay between the time in which the magnet (on the Blood Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B
PBP. T. BA	Delay between the time in which the magnet (on the PBP Pump rotor) closes the circuit of the sensor B and the time in which the magnet closes the circuit of the sensor A
EFFL.T. BA	Delay between the time in which the magnet (on the Effluent Pump rotor) closes the circuit of the sensor B and the time in which the magnet closes the circuit of the sensor A
DIAL. T. BA	Delay between the time in which the magnet (on the Dialysate Pump rotor) closes the circuit of the sensor B and the time in which the magnet closes the circuit of the sensor A
REPL. T. BA	Delay between the time in which the magnet (on the Replacement Pump rotor) closes the circuit of the sensor B and the time in which the magnet closes the circuit of the sensor A
BLOOD. T. BA.	Delay between the time in which the magnet (on the Blood Pump rotor) closes the circuit of the sensor B and the time in which the magnet closes the circuit of the sensor A
PBP. BRAKE.	Not used
EFFL. BRAKE.	Not used
DIAL. BRAKE.	Not used
REPL.BRAKE.	Not used
BLOOD.BRAKE.	Status of the break on the Blood Pump. Possible values displayed are: Enabled/Disabled
PBP. AL. S. A	Not used
EFFL. AL. S. A	Not used
DIAL. AL. S. A	Not used
REPL. AL. S. A	Not used
BLOOD. AL. S. A	Not used

Parameter	Description
PBP. AL. S. B	Not used
EFFL. AL. S. B	Not used
DIAL. AL. S. B	Not used
REPL. AL. S. B	Not used
BLOOD. AL. S. B	Not used
PBP. ENCODER.	Not used
EFFL ENCODER.	Not used
DIAL ENCODER.	Not used
REPL. ENCODER.	Not used
BLOOD. ENCODER.	Value, in rpm, of the Blood Pump speed read by Control side
SC. PBP. CTR AD	PBP scale A/D value read by the Control side
SC. EFF. CTR AD	Effluent scale A/D value read by the Control side
SC. DIA. CTR AD	Dialysate scale A/D value read by the Control side
SC. REP. CTR AD	Replacement scale A/D value read by the Control side
SC. PBP. PRT AD	PBP scale A/D value read by the Protective side
SC. EFF. PRT AD	Effluent scale A/D value read by the Protective side
SC. DIA. PRT AD	Dialysate scale A/D value read by the Protective side
SC. REP. PRT AD	Replacement scale A/D value read by the Protective side
SC. PBP. REFAD1.	PBP scale A/D reference 1 value (1st A/D channel)
SC. EFF. REFAD1.	Effluent scale A/D reference 1 value (1st A/D channel)
SC. DIA. REFAD1	Dialysate scale A/D reference 1 value (1st A/D channel)
SC. REP. REFAD1	Replacement scale A/D reference 1 value (1st A/D channel)
SC. PBP. REFAD2.	PBP scale A/D reference 2 value (2nd A/D channel)
SC. EFF. REFAD2.	Effluent scale A/D reference 2 value (2nd A/D channel)
SC. DIA. REFAD2.	Dialysate scale A/D reference 2 value (2nd A/D channel)
SC. REP. REFAD2.	Replacement scale A/D reference 2 value (2nd A/D channel)
SC. PBP. CTR GR	Weight in grams, on the PBP scale, read by the Control side
SC. EFF. CTR GR	Weight in grams, on the Effluent scale, read by the Control side
SC. DIA. CTR GR	Weight in grams, on the Dialysate scale, read by the Control side
SC. REP. CTR GR	Weight in grams, on the Replacement scale, read by the Control side
SC. PBP. PRT GR	Weight in grams, on the PBP scale, read by the Protective side
SC. EFF. PRT GR	Weight in grams, on the Effluent scale, read by the Protective side

Parameter	Description
SC. DIA. PRT GR	Weight in grams, on the Dialysate scale, read by the Protective side
SC. REP. PRT GR	Weight in grams, on the Replacement scale, read by the Protective side
SC. PBP. SWITCH.	Status of the PBP scale switch (scale open/scale close) Possible values displayed are: Open/Closed
SC. EFF. SWITCH.	Status of the Effluent scale switch (scale open/scale close) Possible values displayed are: Open/Closed
SC. DIA. SWITCH.	Status of the Dialysate scale switch (scale open/scale close) Possible values displayed are: Open/Closed
SC. REP. SWITCH.	Status of the Replacement scale switch (scale open/scale close). Possible values displayed are: Open/Closed
SC. PBP. DIGFIL	Not used
SC. EFF. DIGFIL	Not used
SC. DIA. DIGFIL	Not used
SC. REP. DIGFIL	Not used
SC. PBP. OFFSET.	Not used
SC. EFF. OFFSET.	Not used
SC. DIA. OFFSET.	Not used
SC. REP. OFFSET.	Not used
SC. PBP. CTR ERR	Remaining summed scale error after calibration in grams
SC. EFF. CTR ERR	Remaining summed scale error after calibration in grams
SC. DIA. CTR ERR	Remaining summed scale error after calibration in grams
SC. REP. CTR ERR	Remaining summed scale error after calibration in grams
SC. PBP. PRT ERR	Remaining summed scale error after calibration in grams
SC. EFF. PRT ERR	Remaining summed scale error after calibration in grams
SC. DIA. PRT ERR	Remaining summed scale error after calibration in grams
SC. REP. PRT ERR	Remaining summed scale error after calibration in grams

Second Technical Screen

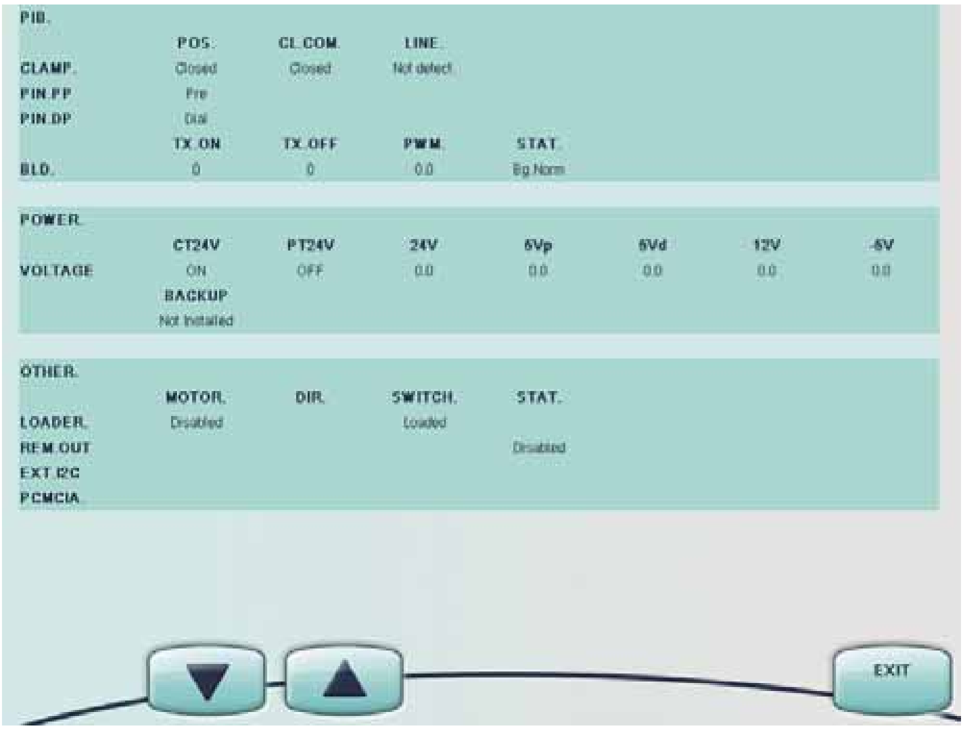


Parameter	Description
ACC. AD VAL	Access pressure A/D value acquired by the transducer
FIL. AD VAL	Filter pressure A/D value acquired by the transducer
EFF. AD VAL	Effluent pressure A/D value acquired by the transducer
5TH. AD VAL	5th Pod pressure A/D value acquired by the transducer
ARPS. AD VAL	Circuit pressure A/D value acquired by the ARPS
RET. AD VAL	Return pressure A/D value acquired by the transducer
ACC. PRES.	Access pressure value read by the Protective side
FIL. PRES.	Filter pressure value read by the Protective side
EFF. PRES.	Effluent pressure value read by the Protective side
5TH. PRES.	5th Pod pressure value read by the Protective side
ARPS. PRES.	ARPS circuit pressure read by the Protective side
RET. PRES.	Return pressure value read by the Protective side
ACC. VALVE.	Access valve status. Possible values displayed are: Open/Closed
FIL. VALVE.	Filter valve status. Possible values displayed are: Open/Closed
EFF. VALVE.	Effluent valve status. Possible values displayed are: Open/Closed
5TH. VALVE.	5th Pod valve status. Possible values displayed are: Open/Closed
ARPS. VALVE.	Not currently used
RET. VALVE.	Return valve status. Possible values displayed are: Open/Closed

Parameter	Description
ARPS. SET.	Not used.
ARPS. DIGFIL.	Not used.
ARPS. MOTOR.	ARPS Motor status. Possible values displayed are: Running, Not running
ARPS. DIR.	ARPS Direction (Decrease = the motor runs in clockwise direction/Increase = the motor runs in counterclockwise direction) Possible values displayed are: Decrease, Increase
ARPS. REFAD1.	ARPS A/D reference 1 value read by the Protective side
ARPS. REFAD2.	ARPS A/D reference 2 value read by the Protective side
ARPS. REFAD3.	ARPS A/D reference 3 value read by the Protective side
ABD. LINE.	Presence of line in the ABD. Possible values displayed are: Line Detected/Not detected
ABD. TROUB.	Malfunction detected in the ABD circuit. Possible values displayed are: ON/OFF
ABD. MAC.B.	Macro Bubble detected by the ABD. Possible values displayed are: ON/OFF
ABD. APSTOP.	Not used
H.PUMP. MANUAL.	Activation of the Manual mode of the Syringe Pump. Possible values displayed are: Enabled/Disabled
H.PUMP. AUTOM.	Activation of the Automatic mode of the Syringe Pump. Possible values displayed are: Enabled/Disabled
H.PUMP SET.	Syringe Pump rate set
H.PUMP F. AD	A/D value of the load applied to the syringe plunger clamp read by the Syringe Pump
H.PUMP F.N	Load applied to the syringe plunger clamp in Newtons (N)
H.PUMP UEOS.	Upper End of stroke of the syringe plunger clamp reached. Possible values displayed are: OFF/ON
H.PUMP LEOS.	Lower End of stroke of the syringe plunger clamp reached. Possible values displayed are: OFF/ON
H.PUMP OVRLD.	Overload condition of the Syringe Pump. Possible values displayed are: OFF/ON
H.PUMP ABSTH.	Threshold of the absolute overload of the Syringe Pump expressed in Newton
H.PUMP SLOPE.	Absolute slope threshold of the Syringe Pump expressed in N/mm
H.PUMP DIR.	Not used
H.PUMP POS.	The position of the carrier, measured from the lower end position, expressed in mm.
H. SYR. STATUS.	Status of the syringe. Possible values displayed are: Loaded/Not loaded
H. SYR. THRLD	Threshold for the detection of a syringe loaded
H. SYR. COUNT.	Counter of the encoder pulses received at the selection of the Syringe control panel UP button when the Syringe Pump is in Manual mode
H. SYR. RAMP.	Not used

Parameter	Description
H. SYR. UP. BUT.	Status of the UP button on the Syringe control panel. Possible values displayed are: Pressed/Released
H. SYR. DN. BUT.	Status of the DOWN button on the Syringe control panel. Possible values displayed are: Pressed/Released

Third Technical Screen

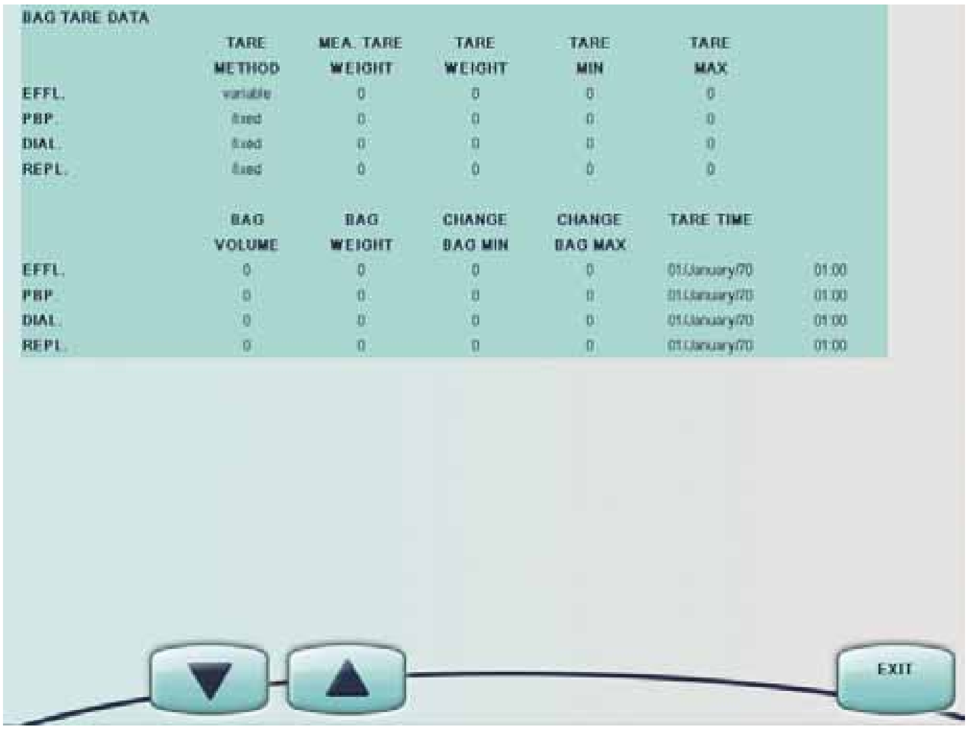


Parameter	Description
CLAMP. POS.	Return clamp status. Possible values displayed are: Open/Closed
PIN.PP POS.	Lower pinch valve position. Possible values displayed are: Pre/Neutral/Post/Undefined
PIN.DP POS.	Upper pinch valve position. Possible values displayed are: Pre/Neutral/Post/Undefined
CLAMP. CL.COM.	Comment sent by the Control side to the Return clamp. Possible values displayed are: Open/Closed
PIN.PP CL.COM.	Not used
PIN.DP CL.COM.	Not used
CLAMP. LINE.	Line presence in the Return line clamp. Possible values displayed are: Line Detected/Not detected
PIN.PP LINE.	Not used
PIN.DP LINE.	Not used.
BLD. TX.ON	BLD A/D value read when the transmitter is ON
BLD. TX.OFF	BLD A/D value read when the transmitter is OFF
BLD. PWM.	PWM value

Parameter	Description
BLD. STAT.	Status of the BLD normalization procedure Possible values displayed are: Bg.Norm M.pwm.BLD Ms.BLD VrA.regst W.A.regDn C.pwmVal Tst.W.stop Test ok Test Fail
VOLTAGE CT24V	Status of the +24V relay in the Power supply (Enabling/Disabling done by the Control side). Possible values displayed are: OFF/ON
VOLTAGE PT24V	Status of the +24V relay in the Power supply (Enabling/Disabling done by the Protective side). Possible values displayed are: OFF/ON
VOLTAGE 24V	+24V voltage value. Value in VDC
VOLTAGE 5Vp	5Vp voltage value. Value in VDC
VOLTAGE 5Vd	5Vd voltage value. Value in VDC
VOLTAGE 12V	+12V voltage value. Value in VDC
VOLTAGE -5V	5V voltage value. Value in VDC
BACKUP	Indicates if Battery backup is installed. Possible values displayed are: Installed/Not Installed
LOADER. MOTOR.	Status of the motor of the Prismaflex disposable set loader. Possible values displayed are: Enable/Disable
REM.OUT MOTOR.	Not used
EXT.I2C MOTOR.	Not used
PCMCIA. MOTOR.	Not used
LOADER. DIR.	Not used
REM.OUT DIR.	Not used
EXT.I2C DIR.	Not used
PCMCIA. DIR.	Not used
LOADER. SWITCH.	Status of the switch of the Prismaflex disposable set loader. Possible values displayed are: Loaded / Not Loaded

Parameter	Description
REM.OUT SWITCH.	Not used
EXT.I2C SWITCH.	Not used
PCMCIA. SWITCH.	Not used
LOADER. STAT.	Not used
REM.OUT STAT.	Status of the remote alarm output. Possible values displayed are: Enabled/Disabled
EXT.I2C STAT.	Not used
PCMCIA. STAT.	Not used

Fourth Technical Screen



Parameter	Description
`Tare method`	Empty Bag Method set in Custom mode. Possible values displayed are: variable/fixed
`Meas_tare weight`	Measured tare weight in grams.
`Tare weight`	Tare weight in grams as calculated/established by Protective.
`Tare min`	Minimum tare in grams as calculated/established by Protective.
`Tare max`	Maximum tare in grams as calculated/established by Protective.
`Bag volume`	Allowed bag volume in ml as set in Custom mode or from Change Bags or Change Bags/Containers screen.
`Bag weight`	Bag weight in grams as measured by Protective at last tare calculation.
`Change bag min`	Minimum weight in grams for a new bag.
`Change bag max`	Maximum weight in grams for a new bag.
`Tare time`	Date and time for last tare calculation.

Fifth Technical Screen

Parameter	Description
SWVERS. CONTROL.	Software version of the Control System.
SWVERS. PLD.	Software version of the PLD Board
SWVERS. CH.PRO.	Software version of the Carrier Board
SWVERS. PROT.	Software version of the Protective Board
SWVERS. P.INF.	Not used
SWVERS. BLOOD.	Old Pump: Not currently used. New Pump: Software version of the Blood Pump
SWVERS. SCALE.	Not used
SWVERS. ARPS.	Software version of the ARPS Board
SWVERS. PIB.	Software version of the PIB Board
SWVERS. LOADER.	Not used
SWVERS. HEPAR.	Software version of the syringe pump
SWVERS. PSB	Software version of the Power Supervision Board
Language	Displays installed language and language package version. Default settings are: English, Default Language.

Sixth Technical Screen

Bar code

The bar code contains information about the setup and configuration of the machine, such as hardware/software configuration and calibration parameters.

The bar code gives valuable information for troubleshooting and complaint handling.

Photograph the bar code

Use a digital camera to be able to take a photograph of the bar code and send it to Gambro. Take the photograph straight from the front. It is important there are no reflections caused by the flash or other light near the display.

This page is intentionally left blank

Chapter 5

Alarms and Troubleshooting

Contents

About this chapter 5:2
Warning Alarms 5:3
- Prismaflex® Control Unit Actions 5:3
- Operator Response 5:3
- Overridden Warning Alarms 5:4

Malfunction Alarms 5:5
- Prismaflex® Control Unit Actions 5:5
- Operator Response 5:5
- Overridden Malfunction Alarms 5:6

Caution Alarms 5:7
- Prismaflex® Control Unit Actions 5:7
- Operator Response 5:7

Advisory Alarms 5:8
- Prismaflex® Control Unit Actions 5:8
- Operator Response 5:8
- Overridden Advisory Alarms 5:8

Alarm Priorities 5:9
- Alarm Priority List 5:9

Troubleshooting 5:14
- About the Troubleshooting Chapter 5:14

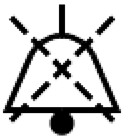
Warning Alarms 5:15
Caution Alarms 5:39
Advisory Alarms 5:48
Malfunction Alarms 5:66
Miscellaneous 5:97
Power Failure 5:101

About this chapter

This chapter describes the different alarms that can occur and how so solve them.

The Prismaflex control unit continually monitors itself and the Prismaflex disposable set for proper functioning during operation. If an abnormal situation occurs, the control unit signals a Warning, Malfunction, Caution, or Advisory alarm.

The operator is notified of an alarm condition via a red or yellow status light, an audible alarm, and an alarm screen on the display. Each alarm screen provides instructions on how to respond to the alarm. Press the *MUTE* softkey to temporarily silence the audible alarm (for 2 minutes).



When applicable, a `Help` screen is available to provide additional information.

Some of the alarms are possible to override. Press *EXAMINE ALARMS* to see the complete list.

Note: *EXAMINE ALARMS* softkey is placed in the `Modify Settings` screen in Run mode.

WARNING

⚠ When responding to any alarm, carefully follow the instructions on the displayed alarm screen and its associated Help screen.

⚠ To clear some alarms, the Prismaflex control unit must override the alarm for a brief time (60 seconds). The alarm screen notifies the operator that the alarm will be overridden if the *OVERRIDE* softkey is pressed. A new alarm for the same condition cannot occur during the override period. Therefore, carefully observe the set and all operation during the override period. If the alarm condition is still present after the override period, the Prismaflex control unit issues a new alarm.

⚠ Do not override the same alarm repeatedly. End treatment and call for service.

⚠ If power is lost to the Prismaflex control unit, the patient can be manually disconnected from the set. If performing a Manual Termination With Blood Return, visually check for air in the blood return line until the patient is disconnected.

⚠ The Prismaflex control unit may not be able to detect disconnections of the set from the patient's catheter. Carefully observe the set and all operation while using the Prismaflex system.

WARNING

Warning Alarms

Warning alarms occur if conditions of possible patient hazard exist that require prompt operator intervention; for example, air bubbles in the return line or extreme positive pressure in the return line.

Prismaflex® Control Unit Actions

The following actions occur during a Warning alarm:

- The Prismaflex control unit enters a “safe state” by stopping all pumps and closing the return line clamp. Treatment is suspended. The patient’s blood does not circulate through the blood flowpath.
- Red flashing light.
- Recurring high sound, 10 sound pulses repeated approx. every 8 seconds until muted.
- Warning screen appears on the display.

Operator Response

The Warning screen gives the operator instructions for responding to the Warning alarm. Appropriate responses are different for each warning.

When the alarm has been cleared, the following occurs:

- Warning screen leaves the display.
- Green light is lit.
- *EXAMINE ALARMS* softkey disappears, unless there are other active alarms.
- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.

Overridden Warning Alarms

To clear some Warning alarms, the Prismaflex control unit must override the alarm for a short period of time. After completing the response instructions given on the Warning screen, the operator presses the *OVERRIDE* softkey. During the override period, the following occurs:

- Warning screen leaves the display.
- Yellow constant light.
- *EXAMINE ALARMS* softkey remains displayed.
- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.

When the override period is complete, the alarm either clears or recurs.

Malfunction Alarms

Malfunction alarms occur if patient safety cannot be monitored due to a failure of the system; for example, failure during self-tests, errors in the software, or hardware failure.

Prismaflex® Control Unit Actions

The following actions occur during a Malfunction alarm:

- The Prismaflex control unit enters a "safe state" by stopping all pumps and closing the return line clamp. Treatment is suspended. The patient's blood does not circulate through the blood flowpath.
- Red flashing light.
- Recurring high sound, 10 sound pulses repeated approx. every 8 seconds until muted.
- Malfunction screen appears on the display.

Operator Response

Some malfunctions can be cleared by the operator; others require service by an authorized service technician. The Malfunction screen gives instructions for responding to the Malfunction alarm. Appropriate responses are different for each malfunction.

When the alarm has been cleared, the following occurs:

- Malfunction screen leaves the display.
- Green light is lit.
- *EXAMINE ALARMS* softkey disappears, unless there are other active alarms.
- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.

If the operator cannot clear a particular Malfunction alarm, it must be cleared in Service mode by an authorized service technician. The `Malfunction` screen gives appropriate instructions.

Overridden Malfunction Alarms

To clear some Malfunction alarms, the Prismaflex control unit must override the alarm for a brief time. After completing the response instructions given on the Malfunction screen, the operator presses the *OVERRIDE* softkey. During the override period, the following occurs:

- Malfunction screen leaves the display.
- Yellow constant light.
- *EXAMINE ALARMS* softkey remains displayed.
- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.

When the override period is complete, the alarm either clears or recurs.

Caution Alarms

Caution alarms occur if a condition exists for which the proper action is to suspend treatment, but it is safe to continue blood and syringe pump flow; for example, the PBP, dialysate or replacement solution bag is empty or the effluent bag is full.

Prismaflex® Control Unit Actions

The following actions occur during a Caution alarm:

- PBP, replacement, dialysate, and effluent pumps stop.
- Blood and syringe pumps continue to operate and the return line clamp remains open. The patient's blood continues to circulate through the blood flowpath, but treatment is suspended.
- Yellow flashing light.
- Recurring medium sound, 3 sound pulses repeated approx. every 11 seconds until muted.
- Caution screen appears on the display.

Operator Response

The Caution screen gives the operator instructions for responding to the Caution alarm. Appropriate responses are different for each caution.

When the alarm has been cleared, the following occurs:

- Caution screen leaves the display.
- Green light is lit.
- *EXAMINE ALARMS* softkey disappears, unless there are other active alarms.
- PBP, replacement, dialysate, and effluent pumps restart within a few seconds.

Advisory Alarms

Advisory alarms occur if a condition exists of which the operator should be aware, but the patient is not at immediate risk. The patient's treatment continues during an Advisory alarm.

Prismaflex® Control Unit Actions

The following actions occur during an Advisory alarm:

- No pumps stop; treatment continues.
- Yellow constant light.
- Recurring low sound, 2 sound pulses repeated approx. every 21 seconds until muted.
- Advisory screen appears on the display.

Operator Response

The Advisory screen gives the operator instructions for responding to the Advisory alarm; appropriate responses are different for each advisory.

When an advisory has been cleared (self-cleared or cleared by the operator), the following occurs:

- Advisory screen leaves the display.
- Green light is lit.
- *EXAMINE ALARMS* softkey disappears, unless there are other active alarms.

Overridden Advisory Alarms

Many Advisory alarms can be overridden by the operator. If an Advisory alarm is overridden, it remains overridden indefinitely. If the overridden alarm is a self-clearing alarm, it clears when the condition no longer exists. If the overridden alarm is not selfclearing, it remains in a list of pending alarms. Pending alarms can be viewed by pressing the *EXAMINE ALARMS* softkey. See "Alarm Priorities" on page 5:9 for more information.

If the operator overrides an Advisory alarm, the following control unit actions occur:

- Advisory screen leaves the display.
- Yellow light remains illuminated.
- *EXAMINE ALARMS* softkey remains displayed.

Alarm Priorities

All alarms are prioritized. This means that if multiple problems exist, only the highest-priority alarm screen is displayed. Clearing the highest-priority alarm causes the second highest-priority alarm screen to be displayed, and so on. As each alarm appears on the display, the operator follows the instructions on the screen in order to respond to the alarm.

The priority for each alarm is shown in the Alarm Priority List.

Whenever an alarm occurs, the *EXAMINE ALARMS* softkey appears and the name of the alarm is stored in a *pending (active) alarms list*. Until the alarm is cleared, the *EXAMINE ALARMS* softkey remains displayed and the alarm name remains in the pending alarms list. Overridden alarms are considered active alarms.

Note: *EXAMINE ALARMS* softkey is placed in the `Modify Settings` screen in Run mode.

The operator can press *EXAMINE ALARMS* to view the list of pending alarms.

Alarm Priority List

Priority	**Alarm Title**
Malfunctions (High Priority)	
1	General System Failure
2	Communication Error
3	Memory Error
4	Pressures Circuit Board
5	Voltage Out of Range
Warnings	
6	Air in Blood
7	Return Disconnection
8	Return Pressure Dropping
9	Set Disconnection
10	Filter Clotted
11	Plasmafilter Clotted
12	HP Cartridge Clotted
13	Blood Leak Detected
14	Access Extremely Negative
15	Return Extremely Positive

Priority	Alarm Title
Warnings	
16	Access Extremely Positive
17	Filter Extremely Positive
18	Power Failure
19	Wrong Set Loaded
20	Effluent Bag Full
21	Bag/Container Empty
22	Bag Volume Incorrect
23	Effluent Bag Incorrect
24	Scale Open
25	Clamped Lines
26	Syringe Line Clamped
27	Syringe Empty
28	Calcium Syringe Empty
29	Calcium Line Clamped
30	Ca Line Not Connected
31	Recirculation Time Exceeded
32	Effluent Bag Full
33	Set-up Error
34	Wrong Set Selected
35	Crossed Lines
36	Clamped Lines
37	Wrong Set Loaded
38	Loading Error
39	Battery Low
40	Unsuitable Ca Solution
41	Effluent Line Not in BLD

Priority	Alarm Title
Malfunctions	
42	Air Detector
43	Clamp Stuck Closed
44	Blood Pump
45	Effluent Pump
46	Replacement Pump
47	Dialysate Pump
48	Replacement 2 Pump
49	PBP Pump
50	Normalization Failed
51	Blood Leak Detector
52	Self-Test Failure
53	Prime Self-Test
54	Syringe Pump
55	Scales
56	Pressure Zero Test
57	Scale Zero Test
58	Checksum Interrupted
59	Custom Data
60	Library Data
61	Cannot Save Custom Data
62	Memory Error
63	Upper Pinch Valve
64	Lower Pinch Valve
65	Scales Circuit Board
66	Effluent Scale Sensor
67	Replacement Scale Sensor
68	Dialysate Scale Sensor
69	PBP Scale Sensor
70	Syringe Not Loaded / Ca Syringe Not Loaded
71	Line in Air Detector
72	Line in Clamp
73	No Line in Air Detector
74	No Line in Clamp
75	Memory Error, code 7
76	Auto Blood Return

Priority	Alarm Title
Caution	
77	Loss Limit Reached/Gain Limit Reached
78	Unresolved Flow Problems
79	Flow Problem
80	TPE Prescription Delivered
81	Effluent Bag Full
82	Bag Empty
83	TMP Excessive
84	TMPa Excessive
85	Bag Volume Incorrect
86	Effluent Bag Incorrect
87	Scale Open
88	Patient Fluid Gain Excessive
89	Anticoagulation Suspended

Priority	Alarm Title
Advisory	
90	Check Access
91	Check Return
92	Blood Flow Stopped
93	Syringe not loaded / Ca Syringe Not Loaded
94	Fluid Pumps Stopped
95	Check Syringe Line
96	Syringe Empty
97	Syringe Line Clamped
98	Calcium Syringe Empty
99	Syringe Almost Empty / Ca Syringe Almost Empty
100	Calcium Line Clamped
101	Ca Line Not Connected
102	Filter is Clotting
103	Plasmafilter is Clotting
104	HP Cartridge is Clotting
105	TMP Too High
106	TMPa Too High
107	Time to Change Set
108	Cannot Detect Return
109	Download Interrupted
110	Anticoagulation Checkpoints
111	Self-Test Overdue
112	Memory Backup
113	MARS Treatment
114	Battery Exhausted
115	Main Power Lost
116	Incomplete Bolus

Troubleshooting

About the Troubleshooting Chapter

The *alarm* screens give online instructions for responding to most alarm situations. Under certain circumstances, however, the *alarm* screens cannot give the necessary detailed instructions. This chapter of the manual provides the additional information that may be needed.

Warning Alarms

Access Extremely Negative

Observation:
Alarm occurs if the access pressure is more negative than the user-controllable "Access Extremely Negative" Warning Limit. or if access pressure is 150 mmHg or more below its operating point.

Note: An operating point is the pressure value when the pressure is considered stable after an event such as an alarm, change of blood flow, etc.

This alarm self-clears if pressure goes back to normal limits within 15 seconds[c]. During the self-clear time the monitor will not give an audible alarm.

Possible cause(s):	**Operator action(s):**
Patient is moving, coughing, or being suctioned.	Wait 15 seconds for self-clearing[c] attempt. Note: If a self-clear attempt fails wait until the pressure is back to normal in the non self-clearing screen, then press *CONTINUE*[a].
Access line clamped, kinked or partially blocked.	Note: If a self-clear attempt fails, wait until the pressure is back to normal in the non self-clearing screen, then press *CONTINUE*[a].
Access catheter clotted or out of position in vein, or blood flow rate too high for the access device.	Flush/reposition access catheter per hospital protocol. Use access sample site to infuse saline to release negative pressure and/or lower blood flow rate. Press *CONTINUE*[a].
Access pressure sensor failed.	End treatment, call service. Note: If the above operator responses do not clear the alarm, the set can be changed and the alarm cleared via *STOP*[b]. If alarm recurs with a new set, end treatment via *STOP*[b]. Call service.

Possible cause(s):	**Service Technician action(s):**
Blood flow rate too high for the access device.	Check Access pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation in diagnose, see next Service action.

	If pressure is correct, check Blood pump flowrate in Service Diagnose, Diagnose Screen – Pumps Diagnose on page 6:26. If value is incorrect, replace the Blood pump.
Access pressure measurement failure. Note: Self-test interruption as a common root cause.	Check the function of the pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. Check the pressure sensors and pressure ARPS circuit for leakage. If leakage is detected, remedy the pressure pod sealing cones, pressure sensors, pressure valves, ARPS pump alt ARPS circuit. If pressure deviation in diagnose, see next Service action.
Access pressure sensor failed.	Perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, replace the pressure sensor.

Access Extremely Positive

Observation:
Alarm occurs if the access pressure is more positive than the user-controllable "Access Extremely Positive" Warning Limit.

Possible cause(s):	**Operator action(s):**
External device (if in use) is delivering blood at a too high pressure.	Reduce the delivery pressure of the external device.
Blood flow rate has been set too low according to the blood pressure delivered by the external device.	Increase blood flow rate. Return to *alarm* screen and press *CONTINUE*.
Access pressure sensor failed.	End treatment. Call service.

Note: If the above operator responses do not clear the alarm, the set can be changed and the alarm cleared via *STOP*[b]. If alarm recurs with a new set, end treatment via *STOP*[b]. Call service.

Access pressure measurement failure.	Perform a self-test to reposition the pressure pod membranes. Clear the alarm to reach *Status* screen. Press *SYSTEM TOOLS* and perform *SELF-TEST*. If the problem persists, change set via *STOP*[b]. If alarm recurs with new set, end treatment via *STOP*. Call service.

Possible cause(s):	**Service Technician action(s):**
Blood flow rate too low for the external device.	Check Access pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure is correct, check Blood pump flowrate in Service Diagnose, Diagnose Screen – Pumps Diagnose on page 6:26. If value is incorrect, replace the Blood pump. If value is correct, continue with pressure sensors.
Access pressure measurement failure. Note: Self-test interruption as a common root cause.	Check the function of the pressure sensors Diagnose Screen – Pressure Pod Reposition on page 6:30. If the values are incorrect, perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If the values are incorrect, replace the pressure sensors(s).
Access pressure sensor failed.	Perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, replace the pressure sensor.

Air in Blood

Possible cause(s):	**Operator action(s):**
Disconnected line, leaking connection, set not fully primed, return line not installed in air detector.	Check blood access and set for possible leakage or disconnection. Remedy possible causes. Press Up arrow until return pressure is NEGATIVE. If unsuccessful, proceed with manual procedure.

	Press *RELEASE CLAMP* to remove air and draw blood from patient into the return line / deaeration chamber. If needed, use arrows to adjust the level of fluid in the chamber. When ready, press *CONTINUE*. Note: If air is present in entire set, press *DISCONNECT* to load and prime a new set.
Air/foam in the tubing.	In case of recurring alarm, open door of air bubble detector and look for air/foam in the tubing; inspect level of fluid in deaeration chamber. Close air bubble detector door. Press *CONTINUE*.

Bag/Container Empty

Observation:
This alarm appears during priming only.

Possible cause(s):	**Operator action(s):**
Identified solution bag is empty[d].	Connect a new bag. Press *CONTINUE*.
Identified solution bag is partially supported (not hanging freely).	Remove partial support. Press *CONTINUE*.

Bag Volume Incorrect

Observation:
Valid only if Variable Empty Bag method is selected.

This alarm appears during priming only.

Possible cause(s):	**Operator action(s):**
Amount of fluid in the identified solution bag does not match the current Allowed Volume.	Choose one of the three options on the *alarm* screen. **Caution:** ! Choose *KEEP BAG* only to use a partially full bag that is of the same total volume capacity as the current Allowed Volume.
No bag on scale.	Place the appropriate bag on the scale. Press *CONTINUE*.

Note: If hanging multiple bags on the scale, the total fluid capacity of all bags on the scale must not exceed the allowed volume for that scale.

Foreign object on scale.	Remove foreign object. Press *CONTINUE*.
Identified solution bag is partially supported (not hanging freely).	Remove partial support. Press *CONTINUE*.

Battery Low

Observation:
Main power is still out and batteries are out of energy.
Applicable when machine configuration includes the back-up battery (check with the local representative for more information). See Power Failure on page 5:101

Possible cause(s):	Operator action(s):
Main power has been lost and battery is out of energy.	If patient is in treatment, press *STOP* softkey to end treatment. If a patient is connected in SETUP mode, press *DISCONNECT* softkey to disconnect the patient. Switch off the machine. If a patient is connected in END mode, press *OVERRIDE* softkey to end the treatment. Switch off the machine.
Machine is unplugged and battery is out of energy.	Connect power cord. Press *STOP* and select *RESUME* to restart the treatment.

Blood Leak Detected

Possible cause(s):	Operator action(s):
Air bubble in effluent line at level of blood leak detector.	Press *OVERRIDE*[a] to dislodge bubble. In case of recurring air bubbles (effluent fluid degassing), check for kink in effluent line and/or reduce ultrafiltration rate.
Effluent line not properly installed in blood leak detector.	Press line into detector from the bottom up and route securely through tubing guides. Press *OVERRIDE*[a]. After alarm clears, press *Normalize BLD* in System Tools screen and follow instructions.

	⚠ **Warning:** The blood leak detector must be re-normalized if the effluent line is removed and then reinserted into the blood leak detector after treatment (Run mode) has started.
Liquid or debris in tubing path through the detector.	Remove line from detector. Using a "flossing" action, clean inside the detector with a lint-free cloth and isopropyl alcohol. Dry thoroughly. Clean effluent line with water and dry thoroughly. Reinsert line into detector and tubing guides. Press *OVERRIDE*[a]. After alarm clears, press *Normalize BLD* in System Tools screen and follow instructions. ⚠ **Warning:** The blood leak detector must be re-normalized if the effluent line is removed and then reinserted into the blood leak detector after treatment (Run mode) has started.
Leak in filter membrane.	Change the set via *STOP*[b]. Send sample of the effluent to blood lab for a cell count.
TPE: Formed elements or lipids in plasma, discolored plasma.	Press *OVERRIDE*[a]. Lower replacement rate and/or patient plasma loss rate. Note: If this does not clear the alarm, the set can be changed via *STOP*[b]. If alarm recurs with a new set and lowered flow rates, discontinue treatment.

Calcium Line Clamped

Possible cause(s):	**Operator action(s):**
The calcium infusion line is clamped.	Unclamp the calcium infusion line. Press *CONTINUE*.
Incorrect installation of calcium infusion line.	Inspect calcium infusion line, remove any clamps, kinks or other obstructions. Use the clip above the syringe pump for the calcium infusion line to avoid kinks. Press *CONTINUE*. Note: In case of recurring alarm, press *CHANGE SYR/LINE* softkey to change both the syringe and the calcium infusion line.

Calcium Syringe Empty

Observation:
This alarm appears during priming only.

Possible cause(s):	Operator action(s):
Calcium syringe is empty.	Press *CHANGE SYR/LINE* softkey and follow the instructions on the screen to install a full syringe and return to *alarm* screen. Press *CONTINUE*.

Ca Line Not Connected

Possible cause(s):	Operator action(s):
The calcium infusion line is not connected to the syringe.	Connect a dedicated calcium infusion line to the syringe. Press *CONTINUE*.
Wrong line connected.	Use only a dedicated infusion line for the calcium infusion when the "Citrate – Calcium, Prismaflex Syringe Pump" method is chosen.
The unused and stowed syringe line on the disposable set is connected to the calcium syringe.	Clamp the unused line on the disposable set and leave it unused during entire treatment when "Citrate – Calcium, Prismaflex Syringe Pump" method is chosen. Press *CHANGE SYR/LINE* softkey and follow the instructions on the screen to connect a dedicated calcium infusion line to the syringe.
A syringe of the wrong size is installed.	Use only a 50 ml syringe of the allowed brand when the "Citrate – Calcium, Prismaflex Syringe Pump" method is chosen.
Air in syringe.	Press *CHANGE SYR/LINE*. Follow instructions to install a full syringe and return to *alarm* screen. Press *CONTINUE*.

Clamped Lines

Possible cause(s):	Operator action(s):
One of the lines is clamped.	Unclamp the line. Press *REPRIME*.
Occluded disposable set.	Press *DISCONNECT*. Change set.
One or more pressures sensors failed.	Press *DISCONNECT*. Call service.

Possible cause(s):	Service Technician action(s):
One or more pressures sensors failed.	If the alarm correspond to the Access or Return line, check the pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If the values are incorrect, replace the pressure sensor(s). If the alarm regards one of the bag lines, check corresponding scale; see Service action for the scale “Weight” alarm (Caution), observation Incorrect Weight Change.

Crossed Lines

Possible cause(s):	Operator action(s):
The lines are crossed or tangled.	Check and correct lines and bags setup. Press *REPRIME*.
Foreign object on scale.	Remove the object. Press *REPRIME*.
One or more scales failed.	Press *DISCONNECT*, turn off the machine. Call service.

Possible cause(s):	Service Technician action(s):
One or more scales failed.	Check the function of the scales in Diagnose Screen – Scale Diagnose on

	page 6:28. If needed, calibrate the scales, see Calibration Screen – Scales Calibration on page 6:61. Run the Prismaflex control unit again, perform a new Prime. If the alarm recurs, replace the scale(s).

Effluent Bag Full

Observation:
This alarm appears during priming only.

Possible cause(s):	**Operator action(s):**
Effluent bag is full.	Connect a new effluent bag via instructions on the *alarm* screen. Press *CONTINUE*.
Foreign object on effluent scale.	Remove foreign object. Press *CONTINUE*.

Effluent Bag Incorrect

Observation:
Effluent Bag volume does not match Allowed Volume.
Cause: a 5000 ml empty bag is hung on scale while Effluent Allowed Volume is 9000 ml.

This alarm appears during priming only.

Possible cause(s):	**Operator action(s):**
A 5000 ml empty bag is hung on the scale while Effluent Allowed Volume is 9000 ml.	Replace the 5000 ml bag hung on the scale with a 9000 ml bag or change the Effluent Allowed Volume by pressing *MODIFY BAG*. Press *CONTINUE*.
No bag on scale.	Place the appropriate bag on the scale. Press *CONTINUE*.
Effluent bag is partially supported (not hanging freely).	Remove partial support. Press *CONTINUE*.

Effluent Line Not in BLD

Possible cause(s):	Operator action(s):
Effluent line of new set is not installed in blood leak detector.	Remedy and press *RETEST*. If alarm recurs, press *DISCONNECT* and load a new set. If alarm recurs with a new set, call for service.
Blood leak detector failed.	Press *DISCONNECT*, remove set. Call service.

Possible cause(s):	Service Technician action(s):
Line in blood leak detector is not empty.	Remedy and press *RETEST*.
Blood leak detector failed.	Check the function of the Blood leak detector in Diagnose Screen – BLD (Blood Leak Detector) on page 6:43. If malfunction, replace the Blood leak detector.

Filter Clotted

Observation:
Filter pressure drop exceeds limit for the filter in use, or both the “Filter is Clotting” Advisory and the “TMP Excessive” Caution limits are reached.
Note: TMP value in the MARSFLUX filter is not considered for this alarm during CRRT MARS therapy; see section “Pressure management” in Prismaflex Operator´s manual.

Possible cause(s):	Operator action(s):
Clots have formed in the filter. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath.	Change the set via *STOP*[b]. Test patient’s clotting parameters and adjust anticoagulant delivery if needed.
Clamped line(s) in blood flowpath.	Unclamp lines. Press *CONTINUE*.
Ultrafiltration rate is too high for filter in use.	Press *CONTINUE* and then reduce replacement solution flow rate and/or PBP solution flow rate and/or patient fluid removal rate.

Pressure measurement failure.	Perform a self-test to reposition the pressure pod membranes.
During "Systemic, Prismaflex syringe pump" anticoagulation: Anticoagulation delivery has failed.	Press *STOP*[b] and change the set. Ensure that syringe is properly installed in syringe pump and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect syringe line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump.
During "Citrate - Calcium" anticoagulation: Citrate delivery has failed.	Press *STOP*[b] and change the set. Ensure that PBP pump works properly. If PBP pump has failed, call service.
During CRRT MARS treatment: The MARS monitor has detected a blood leak.	If blood leak confirmed, press *STOP* and change the set. If not, troubleshoot the MARS monitor and press *CONTINUE*.

Possible cause(s):	**Service Technician action(s):**
Anticoagulation delivery has failed.	Perform a diagnose test of the syringe pump, see Diagnose Screen – Syringe Pump on page 6:36. If diagnose test fails, replace the syringe pump.
PBP pump failure.	Perform a diagnose test of the PBP pump, see Diagnose Screen – Pumps Diagnose on page 6:26. If diagnose test fails, replace the PBP pump.

Filter Extremely Positive

Observation:
Alarm occurs if filter pod pressure is ≥450 mmHg.

Possible cause(s):	**Operator action(s):**
Line between filter pressure pod and filter or line between filter and deaeration chamber is clamped or kinked.	Remedy and press *CONTINUE*.

Machine is operating at high return pressure and clotting has begun in filter.	Press *FLOW SETTINGS* and lower blood flow rate. Check catheter.
Excessive pressure.	Relieve excess pressure in return line by pressing *RELEASE CLAMP*. If desired, lower the blood flow rate, press *CONTINUE*.

Note 1: The *RELEASE CLAMP* key is available only if no other alarm requiring the clamp closed is present[e].

The filter pressure will drop as operation commences. (The appropriate Advisory or Warning alarm occurs when filter clotting becomes problematic.)

Note 2: If the above operator responses do not clear this alarm, the set can be changed via *STOP*[b]. If alarm recurs with new set, end treatment via *STOP*[b]. Call service.

Filter pressure sensor failed.	End treatment via *STOP*[b]. Call service.
During CRRT MARS treatment: The MARS monitor has detected a blood leak.	If blood leak confirmed, press *STOP* and change the set. If not, troubleshoot the MARS monitor and press *CONTINUE*.

Possible cause(s):	**Service Technician action(s):**
Filter pressure measurement failure.	Check the function of the pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation in diagnose, see next Service action.
Filter pressure sensor failed.	Perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, replace the pressure sensor.

HP Cartridge Clotted

Observation:
Filter pressure drop exceeds limit for the HP cartridge in use.

Possible cause(s):	Operator action(s):
Clots have formed in the HP cartridge. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath.	Change the set via *STOP*[b]. Test patient's clotting parameters and adjust anticoagulant delivery if needed.
Clamped line(s) in blood flowpath.	Unclamp lines. Press *CONTINUE*.
During "Systemic, Prismaflex syringe pump" anticoagulation: Anticoagulation delivery has failed.	Press *STOP*[b] and change the set. Ensure that syringe is properly installed in syringe pump and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect syringe line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump.
Pressure measurement failure.	Perform a self-test to reposition the pressure pod membranes.

Possible cause(s):	Service Technician action(s):
Anticoagulation delivery has failed.	Perform a diagnose test of the syringe pump, see Diagnose Screen – Syringe Pump on page 6:36. If diagnose test fails, replace the syringe pump.

Loading Error

Observation:
Not possible to load/unload the set.

Possible cause(s):	Operator action(s):
Pinch valves position not correct.	Press *RETEST* to reposition the pinch valves and clear the alarm.

Plasmafilter Clotted

Observation:
Filter pressure drop exceeds limit for the plasmafilter in use, or both the "Plasmafilter is Clotting" Advisory and the "TMPa Excessive" Caution limits are reached.

Possible cause(s):	Operator action(s):
Clots have formed in the plasmafilter. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath.	Change the set via *STOP*[b]. Test patient's clotting parameters and adjust anticoagulant delivery if needed.
Clamped line(s) in blood flowpath.	Unclamp lines. Press *CONTINUE*.
Ultrafiltration rate is too high for filter in use.	Press *CONTINUE* and then reduce replacement solution flow rate and/or patient plasma loss rate.
Pressure measurement failure.	Perform a self-test to reposition the pressure pod membranes.
During "Systemic, Prismaflex syringe pump" anticoagulation: Anticoagulation delivery has failed.	Press *STOP*[b] and change the set. Ensure that syringe is properly installed in syringe pump and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect syringe line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump.
During "Citrate - Calcium" anticoagulation: Citrate delivery has failed.	Press *STOP*[b] and change the set. Ensure that PBP pump works properly. If PBP pump has failed, call service.

Possible cause(s):	Service Technician action(s):
Anticoagulation delivery has failed.	Perform a diagnose test of the syringe pump, see Diagnose Screen – Syringe Pump on page 6:36. If alarm recurs, replace the syringe pump.
PBP pump failure.	Perform a diagnose test of the PBP pump, see Diagnose Screen – Pumps Diagnose on page 6:26. If diagnose test fails, replace the PBP pump.

Power Failure

Observation:
Power lost for more than 15 seconds after machine entered Run mode.

Possible cause(s):	Operator action(s):
Main power failure; machine suddenly unplugged.	Inspect blood flowpath. If clotted, change the set via *STOP*[b]. If flowpath is not clotted, press *CONTINUE*. (Clears alarm and restarts treatment at same place as when power was lost.) Note: If set was manually unloaded during power loss, either: continue treatment with a new set by pressing *STOP*[b], then *CHANGE SET*, or end the treatment by pressing *STOP*[b], then *END TREATMENT*.

Recirculation Time Exceeded

Possible cause(s):	Operator action(s):
Recirculation Time has exceeded the manufacturer-set limit.	Press *STOP RECIRC.* and resume the treatment.

Return Disconnection

Observation:
Alarm occurs if return pressure is lower than +10 mmHg and the return pressure operating point is higher than +10 mmHg. The alarm reoccurs if the following return pressure operating point is lower than +10 mmHg.

Alarm also occurs once if the operating point is lower than +10 mmHg after an operator induced (re)start of the blood pump. Should this pressure condition persist, it will be indicated by subsequent Advisory Cannot Detect Return alarms.

Note: An operating point is the pressure value when the pressure is considered stable after an event such as an alarm, change of blood flow, etc.

Possible cause(s):	Operator action(s):
Return line or catheter is disconnected.	Make sure return catheter is securely connected to both the return line and the patient. To resume treatment, press *CONTINUE*[a].

Chamber monitor line not properly connected to return pressure port or fluid barrier wet.	Press *STOP*[b] and use *CHANGE SET* to load/prime a new set. If fluid barrier wetting recurs call service.
Blood flowpath obstructed before deaeration chamber.	Remedy, if possible. Press *CONTINUE*. If not possible, press *STOP*[b] and use *CHANGE SET* to load/prime a new set.
Return pressure sensor failed.	End treatment via *STOP*[b]. Call service.

Possible cause(s):	**Service Technician action(s):**
Fluid barrier wet with new set.	Check the pressure sensors and the pressure ARPS circuit for leakage in Diagnose Screen – Pressure Pod Reposition on page 6:30. If leakage is detected, remedy the pressure sensor, pressure valves, ARPS pump alt ARPS circuit. If pressure deviation in diagnose, see next Service action.
Return pressure sensor failed.	Perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, replace the pressure sensor.

Return Extremely Positive

Observation:
Alarm occurs if return pressure is more positive than the user-controllable “Return Extremely Positive” Warning Limit.

This alarm self-clears if pressure goes back to normal limits within the self-clear time and the monitor will not give an audible alarm.

Possible cause(s):	**Operator action(s):**
Patient is moving, coughing, or being suctioned.	Wait 15 seconds for self-clearing[c] attempt. Note: If a self-clear attempt fails wait until the pressure is back to normal in the non self-clearing screen, then press *CONTINUE*[a].
Return line clamped or kinked.	Remedy, and wait for self-clearing attempt

Note: If a self-clear attempt fails, wait until the pressure is back to normal in the non self-clearing screen, then press *RELEASE CLAMP* and then *CONTINUE*[a].

Return catheter clotted or out of position in vein, or blood flow rate too high.	Flush/reposition return catheter per hospital protocol and/or lower the blood flow rate. Relieve excess pressure in return line by pressing *RELEASE CLAMP*. Press *CONTINUE*. Note: The *RELEASE CLAMP* is only available if there is no other alarm requiring clamp closed.
Return pressure sensor failed.	End treatment, call service. If the above operations do not clear the alarm, the set can be changed and the alarm cleared via *STOP*[b]. If alarms recur with a new set, end treatment via *STOP*[b]. Call service.

Return Pressure Dropping

Observation:
This alarm occurs if return pressure is 50 mmHg or 70 mmHg (with blood flow>200ml/min) below its operating point.

Possible cause(s):	**Operator action(s):**
Possible leakage or disconnection of return line or catheter.	Make sure return catheter is securely connected to both the return line and the patient. To resume treatment, press *CONTINUE*[g]
Patient is moving or being moved.	Press *CONTINUE*[g].
Blood flowpath obstructed or leaking before deaeration chamber.	Remedy, if possible. Press *CONTINUE*. If not possible, press *STOP*[b] and use *CHANGE SET* to load/prime a new set.
The hydrophobic membrane is wet, and/or service line is disconnected.	Press *STOP*[b] and use *CHANGE SET* to load/prime a new set. If fluid barrier gets wet again with a new set, call service.
Return pressure sensor failed.	End treatment via *STOP*[b]. Call service.
During CRRT MARS treatment: The MARS monitor has detected a blood leak.	If blood leak confirmed, press *STOP* and change the set. If blood leak not confirmed, troubleshoot the MARS monitor and press *CONTINUE*.

Possible cause(s):	Service Technician action(s):
Fluid barrier wet with new set.	Check the pressure sensors and the pressure ARPS circuit for leakage in Diagnose Screen – Pressure Pod Reposition on page 6:30. If leakage is detected, remedy the pressure sensor, pressure valves, ARPS pump alt ARPS circuit. If pressure deviation in diagnose, see next Service action.
Return pressure sensor failed.	Perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, replace the pressure sensor.

Scale Open

Observation:
This alarm appears during priming only.

Possible cause(s):	Operator action(s):
Impeding object blocking scale from fully closing, bag improperly positioned on hooks, carrying bar not centred on bar tray or handle not rotated down (toward floor).	Inspect and remedy possible causes. Press scale toward machine until it locks into closed position. Press *CONTINUE*.
Scale sensor failed.	Press *DISCONNECT*. Call service.

Possible cause(s):	Service Technician action(s):
Scale sensor failed.	Check the function of the scale sensor in Diagnose Screen – Scale Diagnose on page 6:28. If scale sensor test fails, replace the scale.

Set Disconnection

Observation:
Alarm occurs if filter pressure is lower than +10 mmHg and the filter pressure operating point is higher than +10 mmHg.

Possible cause(s):	**Operator action(s):**
Filter pressure pod not installed or debris in sensor housing.	Clean pod from debris and reinstall pod as applicable. Press *OVERRIDE* to clear alarm and perform self-test through *SYSTEM TOOLS* as to reposition pod membrane. If the pod problem recurs, press *STOP* to change the set. If alarm recurs with new set, end treatment and call service.
Line between blood pump and filter is disconnected.	Make sure the line is securely connected. To resume treatment, press *OVERRIDE*[a].
Blood flowpath is obstructed before filter pressure pod.	Remedy, if possible. Press *OVERRIDE*[a] If not possible, press *STOP* [b] and press*CHANGE SET* to load/prime a new set.
Blood flow rate too low for the access device.	Increase the blood flow rate and press *OVERRIDE*[a].
Filter pressure sensor failed.	End treatment via *STOP*[b]. Call service.
Return line disconnection and failure of return pressure alarm.	Check return line and catheter; remedy as applicable. If fluid barrier wet, press *STOP* and press *CHANGE SET* to load/prime a new set. If fluid barrier is not wet, press *OVERRIDE*[a] to clear alarm and to reach *Status* screen. Press *SYSTEM TOOLS* and perform self-test in order to check return pressure sensor.
Pressure measurement failure.	Perform a self-test to reposition the pressure pod membranes. Clear the alarm to reach *Status* screen. Press *SYSTEM TOOLS* and perform *SELF-TEST*. If the problem persists, change set via *STOP*[b]. If alarm recurs with new set, end treatment via *STOP*. Call service.

Possible cause(s):	Service Technician action(s):
Filter pressure measurement failure.	Check the function of the pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation in diagnose, go to service action for Filter pressure sensor failed.
Blood flow rate too low for the access device.	Check Filter pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation in diagnose, check the pressure sensors and pressure ARPS circuit for leakage in Diagnose Screen – Pressure Pod Reposition on page 6:30. If leakage is detected, remedy the pressure pod sealing cones, the pressure sensor, pressure valves, ARPS pump alt ARPS circuit. If pressure is correct, check Blood pump flowrate in Service Diagnose, Diagnose Screen – Pumps Diagnose on page 6:26. If value is incorrect, replace the Blood pump.
Filter pressure sensor failed.	Perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, replace the pressure sensor.

Set-up Error

Observation:
Alarm occurs if pre-prime self-test fails.

Possible cause(s):	Operator action(s):
Set-up is incorrect.	Check Return line in clamp. Press *RELEASE CLAMP* to reposition. Reinstall the return line in clamp. Check chamber monitor line installation, Filter and Effluent pods installation, clamp on dialysate line. Check that the pressure sensors has not failed. Check that the dialysate pump segment is loaded.

	Check that the syringe line and/or one-way valve are connected. Check that the syringe line is clamped. Check that the right set is loaded. (see HELP) Remedy and press *RETEST*. If alarm still recurs, press *UNLOAD* and load a new set. If alarm recurs with a new set, call service.

Possible cause(s):	**Service Technician action(s):**
Set-up is incorrect.	Check the function of the Return, Filter and Effluent pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, perform calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64alt replace the pressure sensors. Check the function of the Dialysate pump in Diagnose Screen – Pumps Diagnose on page 6:26. If pump malfunction, replace pump. Perform a “Verification of slave pump rotor” test, see point 5 in Component Replacement on page 6:17.

Syringe Empty

Possible cause(s):	**Operator action(s):**
Syringe is empty.	Press *CHANGE SYRINGE*, follow instructions to install a full syringe and return to *alarm* screen. Press *CONTINUE*. Note: A full syringe is required during priming. If anticoagulation of blood flowpath is not desired, syringe should be filled with sterile saline solution.

Syringe Line Clamped

Possible cause(s):	**Operator action(s):**
Syringe line clamped, kinked or obstructed.	Inspect syringe line; remove any clamps, kinks or other obstruction. Press *CONTINUE*[a].

Incorrect installation of syringe line	Reinstall syringe line. Press *CONTINUE*[a].
Alam is recurring.	Press *CHANGE SYRINGE*; follow instructions to change the syringe and return to alarm screen. Then press *CONTINUE*.

Unsuitable Ca solution

Observation:
Alarm occurs after `Confirm Loaded Set` screen if no valid set of initial flow settings with reasonable operating ranges is available when using the selected calcium solution. See the chapter about anticoagulation in Operators manual. *Alarm* screen indicates if selected calcium solution is too diluted or too concentrated.

Possible cause(s):	**Operator action(s):**
The calcium solution selected in custom mode is not suitable for use with the selected therapy or set type.	Press *MODIFY SOLUTION*. Use arrows to select another calcium solution. Press *CONTINUE*. The CONTINUE button will only be available if suitable calcium solution is selected.
Alarm is recurring; no suitable calcium solution is available.	Press *UNLOAD* to load a different set type. Consult physician.

Wrong Set Loaded

Observation:
This set cannot be used with the therapy selected.

Possible cause(s):	**Operator action(s):**
Failure of recognition test.	Check that the set matches the selected therapy. Verify physician prescription for the therapy and set. Press *UNLOAD* to access the `Load Set` Screen. If needed, press *CANCEL* on the `Load Set` Screen, select the prescribed therapy, then load the prescribed set. If needed, remove the set attached to the control unit (wrong set), then load the prescribed set. Note: If alarm occurs repeatedly, do not use the machine until repairs are made.

Possible cause(s):	Service Technician action(s):
Failure of recognition test.	Check that right therapy is unlocked according to the set and to the agreement with the customer. If the alarm occurs repeatedly, check that the Bar code reader is correctly installed and connected to the PC 104 board.

Wrong Set Selected

Possible cause(s):	Operator action(s):
Mix up of high flow and low flow set after Bar Code Reading Failure. At the end of the first priming cycle in case of "Bar code reading failure", the operator has to verify that the loaded set and the prescribed set are the same, by pressing *CONFIRM*.	If loaded set does match set identified on screen, press *CONFIRM*. Otherwise, press *DISCONNECT* and reload set.
Foreign object on scale.	If loaded set does match set identified on screen, press *CONFIRM*. Otherwise, press *DISCONNECT* and reload set.
Return line not connected to effluent bag or effluent bag cock opened.	If loaded set does match set identified on screen, press *CONFIRM*. Otherwise, press *DISCONNECT* and reload set.
Scale failed.	Press *DISCONNECT*, remove set. Call service.

Possible cause(s):	Service Technician action(s):
Scale failed.	Check the function of the scale in Diagnose Screen – Scale Diagnose on page 6:28. If needed, calibrate the scale, see Calibration Screen – Scales Calibration on page 6:61. Run the Prismaflex control unit again, perform a new Prime. If the alarm recurs, replace the scale.

Footnotes

a. *OVERRIDE* briefly overrides the alarm. Monitor closely.

b. *STOP* stops all pumps, clears the alarm and displays the `Stop` screen. The following options are available: resume treatment, change set, end treatment and recirculate.

c. A self-clearing attempt is started if the pressure has returned to normal limits within 15 seconds and there are no other active Warning or Malfunction alarms. If self-clear is unsuccessful, return line clamp closes and blood pump stops. In that case the alarm must be manually cleared by the operator. During the self-clearing period there will be no audible signal. Both for Access and for Return pressure alarms, self-clearing can start only if another self-clearing procedure has not been performed in the last 2 minutes.

d. This alarm occurs when the registered weight is less than the tare of the bag. The tare of each bag is automatically calculated by the control unit depending on the Empty Bag Method setting in Custom mode. If Empty Bag method is set to “Fixed”, the tare of the Dialysate/Replacement2, PBP and Replacement bag is set to a fixed value (default: 230 g). If Variable Empty Bag method is selected, the tare of the Dialysate/Replacement2, PBP and Replacement bag is automatically calculated each time a new bag is loaded.

e. If the *RELEASE CLAMP* softkey is not available and opening of the return clamp is not considered a risk, open the return line clamp using the *STOP* and *RESUME* softkeys. If opening of the return clamp is considered a risk, insert a 21-gauge needle with syringe into the upper red sample site closest to the filter pod to aspirate air/blood until the filter pressure reaches a value lower than 450 mmHg.

f. If the *RELEASE CLAMP* softkey is not available and opening of the return clamp is not considered a risk, open the return line clamp using the *STOP* and *RESUME* softkeys. If opening of the return clamp is considered a risk, insert a 21-gauge needle with syringe into the blue sample site (return line) to aspirate air/blood until the return pressure reaches a value lower than the alarm limit setting.

g. *CONTINUE* resets all operating points and clears the alarm.

Caution Alarms

Anticoagulation Suspended

Observation:
Citrate infusion is stopped because calcium infusion has been interrupted for too long. Citrate – Calcium anticoagulation is suspended. This alarms self-clears once anticoagulation is resumed.

Possible cause(s):	**Operator action(s):**
Calcium syringe empty or not loaded, Calcium line clamped or not connected, fluid pumps stopped.	Press *OVERRIDE* and remedy underlying cause to prevent clotting in the set.
	Note: Calcium infusion requires additional monitoring of patient's parameters. Check prescription.

Bag Empty

Possible cause(s):	**Operator action(s):**
Bag as indicated on screen is empty.	Connect a new bag (see instructions on *alarm* screen). If Variable Empty Bag method is set in Custom mode, it is possible to change to a larger/smaller bag, by pressing *MODIFY BAG* and using arrows to set a new Allowed Volume. Press *CONTINUE* when ready.
Bag partially supported (not hanging freely).	Remove partial support, press *CONTINUE*.
Bag has fallen down.	Connect a new bag (follow on-screen instructions). Press *CONTINUE* when ready.

Bag Volume Incorrect

Observation:
Variable Empty Bag method is selected, and amount of fluid in bag does not match Allowed Volume.

Possible cause(s):	**Operator action(s):**
Amount of fluid in the identified solution bag does not match the current Allowed Volume.	Choose one of the options on the *alarm* screen.

Caution:
Choose *KEEP BAG* only to use a partially full bag that is of the same total volume capacity as the current Allowed Volume.

No bag on scale.	Place the appropriate bag on the scale. Press *CONTINUE*.
Foreign object on scale.	Remove foreign object. Press *CONTINUE*.
Identified solution bag is partially supported (not hanging freely).	Remove partial support. Press *CONTINUE*.

Effluent Bag Full

Possible cause(s):	**Operator action(s):**
Effluent bag is full.	Connect a new effluent bag (see instructions on *alarm* screen). If changing to a larger/smaller bag, press *MODIFY BAG* and use arrows to set a new Allowed Volume. Press *CONTINUE*.
Foreign object on effluent scale.	Remove foreign object. Press *CONTINUE*.

Effluent Bag Incorrect

Observation:
Effluent Bag volume does not match expected volume.

Possible cause(s):	Operator action(s):
A 5000 ml empty bag is hung on the scale while Effluent Allowed Volume is 9000 ml.	Replace the 5000 ml bag hung on the scale with a 9000 ml bag or change the Effluent Allowed Volume by pressing *MODIFY BAG*. Press *CONTINUE*.
No bag on scale.	Place the appropriate bag on the scale. Press *CONTINUE*.

Note: If hanging multiple bags on the scale, the total fluid capacity of all bags on the scale must not exceed the allowed volume for that scale.

Effluent bag is partially supported (not hanging freely).	Remove partial support. Press *CONTINUE*.

Flow Problem

Observation:
Flow problem detected with fluid indicated on screen[c].

Possible cause(s):	Operator action(s):
Closed clamp or major leak on line or bag, bag is swinging, kinked line.	Remedy and press *CONTINUE*.
Effluent drain port not fully closed.	Remedy and press *CONTINUE*.
Bag connector not firmly tightened, if bag connected through Luer.	Make sure the Luer connector is firmely tightened.
Foreign object on scale, bag is partially supported (not hanging freely).	Remove object or partial support. Press *CONTINUE*.
Incorrect puncture of the bag, if bag connected through spike.	Using aseptic technique to make sure that the solution bag is correctly punctured.

Incorrect use of the frangible pin, if required for the particular bag.	Break the frangible pin correctly. Press *CONTINUE*. If the problem persists, replace the solution bag using the *CHANGE BAGS* procedure.
Second compartment of bag not opened, if double compartment bag in use.	Press *CONTINUE* and immediately replace the bag using the *CHANGE BAGS* procedure. Closely monitor the deaeration chamber level since residual air from the fluid line might reach the blood flowpath.
Air bubbles in the solution bag or line.	Check bag connections. Remedy and press *CONTINUE*.
Air bubbles in the effluent fluid.	Check effluent line for kink between pod and pump. Remedy and press *CONTINUE*.
Non breathing spike used with a rigid container.	Replace the non breathing spike with a breathing spike. Press *CONTINUE*.
Line connected to wrong bag or bag on wrong scale.	Make sure that the line is connected to the correct bag. Color-coding of line must match color of used scale.
Non-occlusive pump or scale failure.	Press *STOP* and end the treatment. Call service.
Environment with vibrations.	If the source of vibrations cannot be stopped, press *STOP* and end the treatment. Call service.

Possible cause(s):	**Service Technician action(s):**
Non occlusive Dialysate pump.	Perform a "Verification of slave pump rotor" test, see point 5 inComponent Replacement on page 6:17. Check the pump speed in Diagnose Screen – Pumps Diagnose on page 6:26. If deviation, replace the Dialysate pump.
Dialysate scale failed.	Check the function of the scale in Diagnose Screen – Scale Diagnose on page 6:28. If needed, calibrate the scale, see Calibration Screen – Scales Calibration on page 6:61. Run the Prismaflex control unit again, perform a new Prime. If the alarm recurs, replace the scale.

Environment with vibrations.	Check that the environment is according to the specifications.

Gain Limit Reached

Observation:
The Unintended Patient Fluid Gain exceeded the selected limit and the treatment was therefore permanently suspended for safety reasons. Fluid pumps are stopped and will not re-start; the blood pump continues to run.

Possible cause(s):	Operator action(s):
A flow problem has caused the Prismaflex control unit to infuse excess fluid to the patient: Repeated flow obstructions due to closed clamps or kinked lines; Flow errors due to incorrect use of the acccess port on the effluent bag.	Press *STOP* and end the treatment. If indicated, restart treatment with a new set. Use *HISTORY* to verify exact fluid exchange status at *STOP* time.

Loss Limit Reached

Observation:
The Unintended Patient Fluid Loss exceeded the selected limit and the treatment was therefore permanently suspended for safety reasons. Fluid pumps are stopped and will not re-start; the blood pump continues to run.

Possible cause(s):	Operator action(s):
A flow problem has caused the Prismaflex control unit to pull excess fluid from the patient: Repeated flow obstructions due to closed clamps or kinked lines; Flow errors due to incorrect use of the access port on a solution bag (PBP, dialysate, replacement); Flow errors due to effluent fluid degassing.	Press *STOP* and end the treatment. If indicated, restart treatment with a new set. Use *HISTORY* to verify exact fluid exchange status at *STOP* time.

Patient Fluid Gain Excessive

Possible cause(s):	**Operator action(s):**
PBP fluid input has reached the maximum allowed Patient Fluid Gain for the therapy/set.	Stop PBP infusion and continue therapy without further patient fluid gain: Press *FLOW SETTINGS*, set PBP rate to zero. Continue therapy with further fluid gain for the patient: Press *CONTINUE*. Alarm will recur when Patient Fluid Gain increases 10% beyond the maximum allowed value. End treatment: Press *STOP*[b].

Replacement Container Empty

Possible cause(s):	**Operator action(s):**
Replacement container is empty.	Connect a new replacement container. Press *REPLACEMENT* softkey, use arrows to enter a new container volume. Press *CONTINUE*.
Replacement container partially supported (not hanging freely).	Remove partial support, press *CONTINUE*.
Replacement container has fallen down.	Connect a new replacement container (see instructions on *alarm* screen). Press *CONTINUE* when ready.

Scale Open

Observation:
Scale not properly closed.

Possible cause(s):	**Operator action(s):**
Impeding object blocking scale from fully closing, bag improperly positioned on hooks, carrying bar not centred on bar tray or handle not rotated down (toward floor).	Inspect and remedy possible causes. Press scale toward machine until it locks into closed position. Press *CONTINUE*.
Scale sensor failed.	Press *STOP*and end treatment. Call service[b].

Possible cause(s):	Service Technician action(s):
Scale sensor failed.	Check the function of the scale sensor in Diagnose Screen – Scale Diagnose on page 6:28. If scale sensor test fails, replace the scale.

TMPa Excessive

Observation:
Access transmembrane pressure exceeds the safe limit.

Possible cause(s):	Operator action(s):
Effluent rate is too high. Too much plasma is being removed. (Effluent rate = patient plasma loss rate + replacement fluid rate)	Decrease the replacement fluid or increase blood flow rate. Return to *alarm* screen, press *CONTINUE*.
Plasmafilter pressure drop is increasing, possibly due to insufficient anticoagulation.	Decrease blood flow rate and/or adjust anticoagulation prescription.

TMP Excessive

Observation:
Transmembrane pressure exceeds membrane pressure limit.

Possible cause(s):	Operator action(s):
Ultrafiltration rate (UFR) is too high. Too much fluid is being removed. (UFR = patient fluid removal rate + replacement solution rate + PBP rate)	Decrease the PBP, replacement and/or patient fluid removal rates or, alternatively, increase blood flow rate. Return to *alarm* screen, press *CONTINUE*.
Wrong measurement of filter and effluent pressure.	Clear the alarm by temporarily decreasing UFR. Press *SYSTEM TOOLS* from *Status* screen and perform a self-test. Set previous flow rates back. If alarm recurs decrease UFR or change the set.
Inadequate anticoagulation of the extra corporeal circuit.	Press *STOP* and change the set or test patient's clotting parameters and adjust anticoagulant delivery if needed. Note: Filter Clotted warning occurs when the blood in the filter is clotted.

During CRRT MARS treatment: MARSFLUX filter and diaFLUX filter combined transmembrane pressure exceeds membrane pressure limit.	Decrease replacement and/or patient fluid removal and/or PBP rates. Press *CONTINUE*.

TPE Prescription Delivered

Observation:
Prescribed Total Replacement Volume has been delivered.

Possible cause(s):	Operator action(s):
Total Replacement Input has been achieved.	To continue treatment until remaining replacement fluid is used, press *CONTINUE*. When Replacement Container Empty caution occurs, press *STOP* and End treatment. To set new TPE Prescription Delivered alarm point, press *FLOW SETTINGS*, then increase the Total Replacement Input on the `Enter TPE Prescription` s-creen.

Unresolved Flow Problems

Observation:
Too many attempts to remedy Caution: Flow Problem alarms. Accuracy of patient fluid removal may be compromised.

Possible cause(s):	Operator action(s):
Clearing attempts have exceeded the manufacturer-set limit of 10 tries in 3 hours.	Press *STOP* and end the treatment. If indicated, restart treatment with a new set. Use *HISTORY* to verify exact fluid exchange status at *STOP* time.

Footnotes

a. This alarm occurs when the registered weight is less than the tare of the bag. The tare of each bag is automatically calculated by the control unit depending on the Empty Bag Method setting in Custom mode. If Empty Bag Method is set to “Fixed”, the tare of the Dialysate, PBP, Replacement, Replacement2 bag is set to a fixed value (default: 230 g). If Variable Empty Bag method is selected, the tare of the Dialysate, PBP, Replacement, Replacement2 bag is automatically calculated each time a new bag is loaded.

b. Pressing *STOP* stops all pumps, clears the alarm, and displays the `Stop` screen. The following options are available: resume treatment, change set, end treatment, or temporarily disconnect patient from set.

c. Too many unsuccessful attempts to clear this alarm could lead to error in patient fluid balance/fluid removal that could result in patient injury or death. Verify fluid removal accuracy. In case of discrepancy between the prescribed value and fluid removed, consult physician and discontinue the treatment if required. CRRT: When the error in patient fluid balance/fluid removal exceeds the Patient Fluid Loss/Gain Limit a Caution: Loss Limit Reached alarm or Caution: Gain Limit Reached alarm will occur requiring therapy to be discontinued or the set to be changed.
TPE: After 10 unsuccessful attempts to clear this alarm in less than 3 hours, a Caution: Unresolved Flow Problems alarm will occur requiring therapy to be discontinued or the set to be changed.

Advisory Alarms

Anticoagulation Check Points

Possible cause(s):	**Operator action(s):**
Reminder to monitor patient parameters.	"Citrate-Calcium" anticoagulation methods requires additional monitoring of patient parameters. This advisory occurs at a specific time interval when citrate is used. If "Citrate – Calcium, External Pump" anticoagulation method is selected, ensure proper delivery of calcium using an external syringe / infusion pump. Note: To change this checkpoint interval, use *SYSTEM TOOLS* in *Status* screen. Check with your physician for the occurrence of this advisory.

Battery Exhausted

Observation:
Applicable when machine configuration includes the back-up battery (check with the local representative for more information).
Appears when the power level of the back-up battery is too low.

Possible cause(s):	**Operator action(s):**
Back-up battery is depleted.	Press *OVERRIDE* and continue with setup. Machine needs to remain on for charging the battery at least 4 hours. Note: In case of main power failure before the battery back-up is fully charged again, the machine will operate as if no battery back-up was installed. See “Power Failure” on page 5:101 for more information.
Alarm recurs due to old battery or broken internal wiring.	Leave the machine on or operate for more than 24 hours. If the alarm does not self-clear within 24 hours, call service.

Possible cause(s):	Service Technician action(s):
Alarm recurs due to old battery or broken internal wiring.	Check the connection battery wiring. Remedy, if necessary. Check the recharge capacity of the battery. If malfunction, replace the battery.

Blood Flow Stopped

Observation:
Machine has been left in the Stop screen for 60 seconds.

Possible cause(s):	Operator action(s):
Machine left in the Stop screen for more than 60 seconds (all pumps stopped).	Inspect blood flowpath for signs of clotting. If clotted, change the set. Press *CONTINUE* to clear alarm and return to the Stop screen, then choose *CHANGE SET*. If flowpath not clotted, press *CONTINUE* to clear alarm and return to the Stop screen.

Calcium Line Clamped

Possible cause(s):	Operator action(s):
Calcium line is clamped.	Unclamp the calcium infusion line. Press *CONTINUE*.
The central venous access on the patient is clamped.	Unclamp the central venous access on the patient.
The central venous access on the patient is obstructed by clots or sticks fast to the intima of the vein.	Check patient access patency for potential obstructions. Consult a physician for assessment of the central venous catheter.
Incorrect installation of syringe line.	Inspect calcium infusion line, remove any clamps, kinks or other obstructions. Use the clip above the syringe pump for the calcium infusion line to avoid kinks. Press *CONTINUE*.
	Note: In case of recurring alarm, press *CHANGE SYR/LINE* softkey to change both the syringe and the calcium line.

Calcium Syringe Empty

Possible cause(s):	**Operator action(s):**
Calcium syringe is empty.	Press *CHANGE SYR/LINE* softkey and follow the instructions on the screen to install a full syringe. Then return to *alarm* screen and press *CONTINUE*.
	Note: Use only a 50 ml syringe of the allowed brand when the “Citrate – Calcium, Prismaflex Syringe Pump” method is chosen.

Ca Line Not Connected

Possible cause(s):	**Operator action(s):**
Calcium line is not connected to the syringe.	Connect a dedicated calcium infusion line to the syringe. Press *CONTINUE*.
Wrong line connected.	Use only a dedicated infusion line for the calcium infusion when the “Citrate – Calcium, Prismaflex Syringe Pump” method is chosen.
The unused syringe line on the disposable set is connected to the calcium syringe.	Clamp the unused syringe line on the disposable set and left unused during entire treatment when “Citrate – Calcium, Prismaflex Syringe Pump” method is chosen. Press *CHANGE SYR/LINE* softkey and follow the instructions on the screen to connect a dedicated calcium infusion line to the syringe.
A syringe of the wrong size is installed.	Use only a 50 ml syringe of the allowed brand when the “Citrate – Calcium, Prismaflex Syringe Pump” method is chosen.
Air in syringe.	Press *CHANGE SYR/LINE*. Follow instructions to install a full syringe and return to *alarm* screen. Press *CONTINUE*.
Missing non-return valve on calcium infusion line.	Press *CHANGE SYR/LINE*. Follow instructions to install a new calcium infusion line with a non-return valve and return to *alarm* screen. Press *CONTINUE*.

Cannot Detect Return

Observation:
This alarm occurs when the return pressure operating point is more negative than +10 mmHg.
Machine is unable to detect return line and catheter disconnections.

Possible cause(s):	Operator action(s):
Return line or catheter is disconnected.	Make sure return catheter is securely connected to both the return line and the patient. To override this alarm, press *OVERRIDE*.
Catheter size too large or blood flow too low.	If catheter size is too large for the prescribed blood flow rate, consider to change to a smaller catheter. If compatible with prescription, press *FLOW SETTINGS* and increase the blood flow rate. When back in the alarm screen, press *OVERRIDE*.
Chamber monitor line not securely connected to return pressure port.	If the fluid barrier is not damaged, secure monitor line to the luer lock of the return pressure port and press *OVERRIDE*. If the fluid barrier is damaged, change the set (press *STOP*, then *CHANGE SET*.)
Return pressure sensor failed.	End treatment via *STOP*[b]. Call service.

Possible cause(s):	Service Technician action(s):
Return pressure sensor failed.	Check Return pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure is correct, check Blood pump flowrate in Service Diagnose, Diagnose Screen – Pumps Diagnose on page 6:26. If value is incorrect, replace the Blood pump. Check the pressure sensors and pressure ARPS circuit for leakage in Diagnose Screen – Pressure Pod Reposition on page 6:30. If leakage is detected, remedy the pressure sensor, pressure valves, ARPS pump alt ARPS circuit. Perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30.

If pressure deviation, replace the pressure sensor.

Ca Syringe Almost Empty

Possible cause(s):	**Operator action(s):**
Calcium syringe will be empty in 5 minutes.	To install a full syringe when this advisory appears, press *CHANGE SYR/LINE* and follow instructions on the screen. Then return to *alarm* screen and press *CONTINUE*.

Ca Syringe Not Loaded

Possible cause(s):	**Operator action(s):**
The calcium syringe is not loaded.	Press the *CHANGE SYR/LINE* softkey to load a calcium syringe. Then press *RETEST* to restart Syringe Test. If failure recurs, end treatment via *DISCONNECT*. Call service.

Possible cause(s):	**Service Technician action(s):**
The calcium syringe is not loaded although the “Citrate with integrated calcium” method has been selected.	Check the function of the syringe pump in Diagnose Screen – Syringe Pump on page 6:36. Perform a calibration, see Calibration Screen – Syringe Pump Calibration on page 6:66. If malfunction, replace the syringe pump.

Check Access

Observation:
When running with an operating point below –10 mmHg, this alarm occurs if access pressure is 50 mmHg or 70 mmHg (if blood flow>200 ml/min) above or below its operating point, or if the pressure rises above 0 mmHg.

When running with an operating point in the range between –10 mmHg and +20 mmHg, this alarm occurs if the access pressure is 50 mmHg or 70 mmHg (if blood flow>200 ml/min) below its operating point, or if the access pressure is 10 mmHg or more above its operating point.

When running with an operating point above +20 mmHg, this alarm occurs if the access pressure drops below +10 mmHg.

NOTE: An operating point is the pressure value when the pressure is considered stable after an event (alarm, change of blood flow, etc).

Possible cause(s):	**Operator action(s):**
Possible leakage or disconnection of access line or catheter.	Make sure access line is securely connected to catheter/blood source. Remedy, press *CONTINUE*[a].
Possible kink or obstruction in access line or catheter.	Remedy, press *CONTINUE*[a].
Patient is coughing or being moved.	Press *CONTINUE*[a].
Catheter is clotted or out of position.	Check the position of the catheter in the vein.
Blood flow rate is too high.	Decrease blood flow rate, return to alarm screen and press *CONTINUE*[a].
Blood flowpath is obstructed after access pressure pod.	Remedy, if possible. Press *CONTINUE*[a]. If not possible, press *STOP*[b] and use *CHANGE SET* to load/prime a new set.

Check Return

Observation:
This alarm occurs if return pressure is 50 mmHg or 70 mmHg (if blood flow>200ml/min) above its operating point.

NOTE: An operating point is the pressure value when the pressure is considered stable after an event (alarm, change of blood flow, etc).

Possible cause(s):	**Operator action(s):**
Possible kink or obstruction in return line or catheter.	Remedy, press *CONTINUE*[g].
Patient is moving.	Press *CONTINUE*[g].
Catheter is clotted or out of position in vein.	Remedy, press *CONTINUE*[g].
Blood flow rate is too high.	Decrease blood flow rate, return to alarm screen and press *CONTINUE*. This alarm self-clears once condition no longer exists.

Check Syringe Line

Observation:
Alarm occurs when pressure exerted by syringe pump indicates syringe line may be clamped. All pumps are stopped while confirmation of clamping is in progress. This alarm self-clears when condition no longer exists.

Note: If this alarm is not cleared within 8 seconds the Advisory: Syringe Line Clamped alarm occurs.

Download Interrupted

Observation:
Download of history data to the technical data card has failed.

Possible cause(s):	**Operator action(s):**
The technical data card is full.	Insert an empty technical data card into the technical data card holder. Press *DOWNLD DATA* to retry downloading the history data.
There is no technical data card in the technical data card holder or the technical data card in the holder is damaged.	Insert a new technical data card into the technical data card holder. Press *DOWNLD DATA* to retry downloading the history data.
Internal malfunction related to the technical data card holder/reader.	Press *CONTINUE* to clear the alarm and proceed without downloading history data. If alarm recurs during subsequent treatments, call service.

Possible cause(s):	**Service Technician action(s):**
Internal malfunction related to the technical data card holder/reader.	Check the function of the PCMCIA board in Diagnose Screen – Communication on page 6:45. If malfunction, replace the board.

Filter is Clotting

Observation:
Increasing TMP and/or Pressure Drop.

Note: TMP value in the MARSFLUX filter is not considered for this alarm during CRRT MARS therapy.

Possible cause(s):	Operator action(s):
Inadequate anticoagulation of the extra corporeal circuit.	Press *STOP*, change the set or test patient's clotting parameters and adjust anticoagulant delivery if needed. The Warning: Filter Clotted alarm occurs when the blood in the filter is clotted.
Ultrafiltration is too high.	Lower TMP by: (a) decreasing the PBP, replacement and/or patient fluid removal rates; (b) increasing the blood flow rate. Press *OVERRIDE*[c]; continue to monitor the set.
Kinked lines in blood flowpath.	Remedy and press *OVERRIDE*[c].
If syringe pump is being used for anticoagulation, syringe may be incorrectly installed or syringe pump may have failed.	Ensure syringe is properly installed in syringe pump holder and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect syringe line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump.
Air leak between deaeration chamber monitor line and return pressure sensor.	If the fluid barrier is not wet with blood, secure monitor line to the luer lock of the return pressure port and press *OVERRIDE*. If the fluid barrier is wet with blood, press *STOP* and change the set.
Wrong measurement of filter or effluent pressure.	Press OVERRIDE to reach *Status* screen. Press SYSTEM TOOLS and perform a self-test.
Filter, effluent or return pressure sensor failed.	Press *OVERRIDE* to reach *Status* screen. Press *SYSTEM TOOLS* and perform a self-test. If pressure sensor failure is confirmed, end the treatment and call service.

Possible cause(s):	Service Technician action(s):
Syringe pump may have failed.	Check the function of the syringe pump in Diagnose Screen – Syringe Pump on page 6:36. Perform a calibration, see Calibration Screen – Syringe Pump Calibration on page 6:66. If malfunction, replace the syringe pump.

Filter, Effluent or Return pressure sensor failed.	Check the function of the pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation in diagnose perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, replace the pressure sensor.

Fluid Pumps Stopped

Possible cause(s):	**Operator action(s):**
Citrate anticoagulation is used and fluid pumps have stopped for more than 10 minutes. Not applicable to "Citrate – Calcium, Prismaflex Syringe Pump" anticoagulation method.	Remedy the cause of interruption. Additional monitoring of patient's laboratory chemistry must be performed on patient: ionized calcium (Ca^{2+})

HP Cartridge is Clotting

Observation:
Increasing Pressure Drop.

Possible cause(s):	**Operator action(s):**
Inadequate anticoagulation of the extra corporeal circuit.	Press *STOP*, change the set or test patient's clotting parameters and adjust if needed.
Kinked lines in blood flowpath.	Remedy and press *OVERRIDE*[c].
If syringe pump is being used for anticoagulation, syringe may be incorrectly installed or syringe pump may have failed.	Ensure syringe is properly installed in syringe pump holder and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect syringe line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump.
Air leak between deaeration chamber monitor line and return pressure sensor.	If the fluid barrier is not wet with blood, secure monitor line to the luer lock of the return pressure port and press *OVERRIDE*. If the fluid barrier is wet with blood, press *STOP* and change the set.

Filter or return pressure sensor failed.	Clear the alarm to reach *Status* screen. Press *SYSTEM TOOLS* and perform *SELF-TEST*. If the pod problem is not solved, press *STOP* and end the treatment. Turn off machine. Call for service. Or operator's action directs wrong measurement.
Wrong measurement of Filter pressure.	End treatment by pressing *STOP*. Call service.

Possible cause(s):	**Service Technician action(s):**
Syringe pump may have failed.	Check the function of the syringe pump in Diagnose Screen – Syringe Pump on page 6:36. Perform a calibration, see Calibration Screen – Syringe Pump Calibration on page 6:66. If malfunction, replace the syringe pump.
Wrong measurement of Filter pressure.	Check the function of the pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation in diagnose, see next Service action.
Filter or Return pressure sensor failed.	Perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, replace the pressure sensor.

Incomplete Bolus

Observation:
Appears when a bolus is interrupted. The blood pump has been stopped, either by the operator or another alarm.

Possible cause(s):	**Operator action(s):**
An anticoagulation bolus could not be completed.	Check patient´s anticoagulation status. If indicated, administer not delivered volume.

Main Power Lost

Observation:
Main power is lost and system operates on battery backup.

Possible cause(s):	**Operator action(s):**
Power Cord is not connected.	Reconnect the power cord. Press *OVERRIDE* to continue treatment until the Warning: Battery Low alarm occurs. This alarm self-clears when condition no longer exists.

MARS Treatment

Possible cause(s):	**Operator action(s):**
CRRT MARS treatment ongoing for more than 1 minute.	Set the MARS pump to the prescribed flow rate and press the *START* softkey on the MARS monitor. Press *CONTINUE* on the Prismaflex screen to return to *Status* screen. Make sure that all blue clamps are open.

Memory Back-Up

Observation:
Applicable when machine configuration does not include the back-up battery (check with the local representative for more information).

Possible cause(s):	**Operator action(s):**
Memory back-up battery is depleted.	Press *OVERRIDE*[c] and continue with setup. Machine needs to remain on for charging the battery at least 4 hours. Note: In case of main power lost before the battery is charged again, the machine will stop. When resuming power, machine will start up with `Query screen`. Select *NEW PRIME* or *CONTINUE* and follow the instructions on the screen.
Alarm recurs due to old battery or broken internal wiring.	Leave the machine on or operate for more than 24 hours. If the alarm does not self-clear within 24 hours, call service.

Plasmafilter is Clotting

Observation:
Increasing Pressure Drop.

Possible cause(s):	Operator action(s):
Inadequate anticoagulation of the extra corporeal circuit.	Press *STOP*, change the set or test patient's clotting parameters and adjust if needed.
Note: The Warning: Plasmafilter clotted alarm occurs when the blood in the Plasmafilter is clotted.	
Blood flow rate is too high or plasmafiltration rate is too high.	Decrease blood flow rate or decrease PBP and/or replacement flow rates[c].
Kinked lines in blood flowpath.	Remedy and press *OVERRIDE*[c].
If syringe pump is being used for anticoagulation, syringe may be incorrectly installed or syringe pump may have failed.	Ensure syringe is properly installed in syringe pump holder and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect syringe line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump.
Air leak between deaeration chamber monitor line and return pressure sensor.	If the fluid barrier is not wet with blood, secure monitor line to the luer lock of the return pressure port and press *OVERRIDE*. If the fluid barrier is wet with blood, press *STOP* and change the set.
Filter or return pressure sensor failed.	Clear the alarm to reach *Status* screen. Press *SYSTEM TOOLS* and perform *SELF-TEST*. If the pod problem is not solved, press *STOP* and end the treatment. Turn off machine. Call for service.
Wrong measurement of filter or effluent pressure.	End treatment by pressing *STOP*. Call service.

Possible cause(s):	Service Technician action(s):
Syringe pump may have failed.	Check the function of the syringe pump in Diagnose Screen – Syringe Pump on page 6:36. Perform a calibration, see Calibration Screen – Syringe Pump Calibration on page 6:66.

	If malfunction, replace the syringe pump.
Wrong measurement of Filter or Effluent pressure.	Check the function of the pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation in diagnose, see next Service action.
Filter or return pressure sensor failed.	Perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, replace the pressure sensor.

Self-Test Overdue

Observation:
Periodic self-test failed completion within the last 150 minutes of treatment.

Possible cause(s):	**Operator action(s):**
Test was interrupted by secondary alarms.	Press *OVERRIDE*; remedy root cause of secondary alarms (e.g. access problems). Self-test will start automatically.
Test was interrupted by operator interventions (including update of prescription settings, and bag or syringe changes)	Press *OVERRIDE*; postpone operator interventions and return to `Status` screen, if possible. Self-test will start automatically.
Test was repeatedly overridden by operator.	Press *OVERRIDE*; self-test will start automatically.

Syringe Almost Empty

Possible cause(s):	**Operator action(s):**
Syringe will be empty in 5 min.	To install a full syringe when this advisory appears, press *CHANGE SYRINGE* and follow instructions on screen. Then return to *alarm* screen and press *CONTINUE*.

Syringe Empty

Possible cause(s):	Operator action(s):
Syringe pump is in end-of-travel position, indicating that syringe is empty.	Press *CHANGE SYRINGE*, follow instructions to install a full syringe, press *CONTINUE*. Note: Install only the allowed syringe (size/brand specified in Custom mode). If desired, continue without syringe delivery. To do this: Press *ANTICOAG SETTINGS*, change to “`Continuous, 0 ml/h`”; return to *alarm* screen. Push plunger clamp release button to release syringe pump from end-of-travel position. Press *CONTINUE* and alarm clears.

Syringe Line Clamped

Possible cause(s):	Operator action(s):
Syringe line on the disposable set is clamped, kinked or obstructed in another way.	Inspect syringe line; remove any clamps; kinks, or other obstructions. Press *CONTINUE*.
Incorrect installation of syringe line.	Reinstall syringe line. Press *CONTINUE*.
Alarm is recurring.	Press *CHANGE SYRINGE*; follow instruction to change the syringe and return to alarm screen. Then Press *CONTINUE*.

Syringe Not Loaded

Possible cause(s):	Operator action(s):
The syringe is not loaded after Syringe Test has been performed.	Press *CHANGE SYRINGE*, follow instructions to load the syringe and return to *alarm* screen. Press *RETEST* to restart Syringe Test. If failure recurs, press *DISCONNECT*, call service and report failure.

Possible cause(s):	Service Technician action(s):
The syringe pump failed.	Check the function of the syringe pump in Diagnose Screen – Syringe Pump on page 6:36. Perform a calibration, see Calibration Screen – Syringe Pump Calibration on page 6:66. If malfunction, replace the syringe pump.

Time to Change Set

Observation:
Hours of use have reached the operator-set “Time to Change Set” limit for this therapy/set combination.

Possible cause(s):	Operator action(s):
A “Time to Change Set” advisory limit has been reached.	Press *STOP*[e] and change the set or press *OVERRIDE* and continue to monitor the set[f].

Warning:
The Prismaflex disposable set must be changed after 72 hours of use. Continued use beyond this limit could result in rupture of the pump segments.
Note: To ensure adequate filter performance, it is recommended that CRRT disposable sets are changed every 24 hours of use.

During CRRT MARS treatment: A “Time to Change Set” advisory limit has been reached.	Press *STOP*[e] and change the disposable sets on both the Prismaflex control unit and the MARS monitor or press *OVERRIDE* and continue to monitor the set[f].

Note: Do not use the X-MARS kit beyond 24 hours. The adsorption columns (diaMARS IE 250 and diaMARS AC 250) are likely to be saturated after this operating time.

TMPa Too High

Observation:
Access transmembrane pressure has reached user-set pressure limit.

Possible cause(s):	Operator action(s):
Inadequate anticoagulation of the extra corporeal circuit.	Press *STOP*, change the set or test patient’s clotting parameters and adjust if needed.

Note: The Warning: Plasmafilter clotted alarm occurs when the blood in the Plasmafilter is clotted.

Blood flow rate is too high or plasmafiltration rate is too high.	Decrease blood flow rate or decrease PBP and/or replacement flow rates[c].
Kinked lines in blood flowpath.	Remedy and press *OVERRIDE*[c].
If syringe pump is being used for anticoagulation, syringe may be incorrectly installed or syringe pump may have failed.	Ensure syringe is properly installed in syringe pump holder and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect syringe line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump.
Filter or effluent pressure sensor failed.	Clear the alarm to reach *Status* screen. Press *SYSTEM TOOLS* and perform *SELF-TEST*. If the pod problem is not solved, press *STOP* and end the treatment. Turn off machine. Call for service. Or operator's action directs wrong measurement.

Possible cause(s):	**Service Technician action(s):**
Syringe pump may have failed.	Check the function of the syringe pump in Diagnose Screen – Syringe Pump on page 6:36. Perform a calibration, see Calibration Screen – Syringe Pump Calibration on page 6:66. If malfunction, replace the syringe pump.
Filter or Effluent sensor failed.	Perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, replace the pressure sensor.

TMP Too High

Observation:
Transmembrane pressure has reached user-set pressure limit.

Possible cause(s):	**Operator action(s):**
Ultrafiltration rate (UFR) is too high for the present blood flow rate. (UFR = patient fluid removal rate + replacement solution rate + PBP rate)	Decrease the replacement and/or patient fluid removal flow rates and/or PBP or increase the blood flow rate. Return to *alarm* screen and press *OVERRIDE*[c].
Inadequate anticoagulation of the extra corporeal circuit.	Press *STOP*, change the set or test patient's clotting parameters and adjust anticoagulant delivery if needed. Note: The Warning: Filter Clotted alarm occurs when the blood in the filter is clotted.
Kinked lines in blood flowpath.	Remedy and press *OVERRIDE*[c].
If syringe pump is being used for anticoagulation, syringe may be incorrectly installed or syringe pump may have failed.	Ensure syringe is properly installed in syringe pump holder and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect syringe line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump.
Air leak between deaeration chamber monitor line and return pressure sensor.	If the fluid barrier is not wet with blood, secure monitor line to the luer lock of the return pressure port and press *OVERRIDE*. If the fluid barrier is wet with blood, press *STOP* and change the set.
Filter or effluent pod failure.	Clear the alarm to reach *Status* screen. Press *SYSTEM TOOLS* and perform *SELF-TEST*. If the pod problem is not solved, press *STOP* and change the set.
Filter or effluent pressure sensor failed.	Clear the alarm to reach *Status* screen. Press *SYSTEM TOOLS* and perform *SELF-TEST*. If the pressure problem is not solved, press *STOP* and end the treatment. Turn off machine. Call for service.
Wrong measurement of filter or effluent pressure.	End treatment by pressing *STOP*. Call service.

During CRRT MARS treatment: MARSFLUX filter and diaFLUX filter transmembrane pressure has reached user-set pressure limit.	Decrease the replacement and/or patient fluid removal and/or PBP rates.

Possible cause(s):	**Service Technician action(s):**
Syringe pump may have failed.	Check the function of the syringe pump in Diagnose Screen – Syringe Pump on page 6:36. Perform a calibration, see Calibration Screen – Syringe Pump Calibration on page 6:66. If malfunction, replace the syringe pump.
Wrong measurement of Filter or Effluent pressure.	Check the function of the pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation in diagnose, see next Service action.
Filter or Effluent pressure sensor failed.	Perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. Check the pressure in Diagnose Screen – Pressure Pod Reposition on page 6:30. If pressure deviation, replace the pressure sensor.

Footnotes

a. *CONTINUE* clears the alarm and resets all operating points except for the return pressure operating point if it is above +10 mmHg.
b. Pressing *STOP* stops all pumps, clears the alarm, and displays the `Stop` screen. The following options are available: resume treatment, change set, end treatment, or temporarily disconnect patient and recirculate sterile saline though set.
c. Alarm can also be overridden if operator decides action is not necessary at this time. Alarm self-clears when condition no longer exists.
d. Too many unsuccessful attempts to clear this alarm could lead to error in patient fluid balance/fluid removal that could result in patient injury or death. If alarm reoccurs, press *HISTORY* and verify fluid removal accuracy. In case of discrepancy between the prescribed value and fluid removed, consult physician and discontinue the treatment if required.
e. Pressing *STOP* stops all pumps and displays the `Stop` screen. The set can be changed by pressing *CHANGE SET* on the `Stop` screen. Alarm clears when set is unloaded.
f. Alarm can also be overridden if operator decides action is not necessary at this time. Alarm clears when set is unloaded.
g. *CONTINUE* clears the alarm and resets all operating points.

Malfunction Alarms

Air Detector

Possible cause(s):	Operator action(s):
Air bubble detector failed self-tests.	Press *RETEST*. If alarm does not clear, end treatment via *DISCONNECT* or manually[a]. Call service. Do not use device until serviced.
Return line not installed or improperly installed in air bubble detector.	Install return line in air bubble detector. When ready, press *CONTINUE*.

Possible cause(s):	Service Technician action(s):
Air bubble detector failed self-tests.	Check the functions of the air bubble detector in Diagnose Screen – Air Detector on page 6:34. Perform a calibration, see Calibration Screen – Air Detector on page 6:85 If malfunction, replace the Air bubble detector.

Auto Blood Return

Possible cause(s):	Operator action(s):
Blood return volume incongruence.	End treatment via *DISCONNECT*. If alarm recurs, call service.

Blood Leak Detector

Observation:
Effluent line not properly installed in blood leak detector. Blood leak detector failed self-tests.

Possible cause(s):	Operator action(s):
Effluent line is not installed, is improperly installed, or is removed from detector.	Press line into detector from bottom up; route through tubing guides. Press *RETEST*.

Room or sun light.	Protect BLD from light source.
Liquid or debris in tubing path through the detector.	Remove line from detector. Using a "flossing" action, clean inside the detector with a lint-free cloth and isopropyl alcohol. Dry thoroughly. Clean effluent line with water and dry thoroughly. Reinsert line into detector and tubing guides. Press *RETEST*. ⚠ **Warning:** The blood leak detector must be re-normalized if the effluent line is removed and then reinserted into the blood leak detector after treatment (Run mode) has started.
Blood leak detector failed.	If alarm does not clear, change set via *CHANGE SET* or end treatment via *DISCONNECT*[a]. Call service.

Possible cause(s):	**Service Technician action(s):**
Blood leak detector failed.	Check the function of the Blood leak detector in Diagnose Screen – BLD (Blood Leak Detector) on page 6:43. If malfunction, replace the Blood leak detector.

Blood Pump

Observation:
Rate of Blood pump is incorrect.

Possible cause(s):	**Operator action(s):**
Momentary problem with pump roller or pump segment in raceway.	Press *CONTINUE*.
Impeding object, clamped line or kinked line in pump raceway; thumb screw in center of rotor has loosened.	If alarm recurs, end treatment: Press *CONTINUE*. When `Status` screen appears, immediately press *STOP*. On `Stop` screen, choose *END TREATMENT* and follow the instructions to disconnect patient and unload set. Call service to remedy/clear alarm[b].

Pump failed.	Call for service.

Possible cause(s):	Service Technician action(s):
Thumb screw in center of rotor has loosened.	Check the screw, remedy if needed.
Pump failed.	Check the function of the Blood pump in Diagnose Screen – Pumps Diagnose on page 6:26. If malfunction, replace the Blood pump.

Cannot Save Custom Data

Possible cause(s):	Operator action(s):
Error in saving newly customized values.	Press *EXIT CUSTOM*. If desired, return to Custom mode, and try again to customize. If alarm recurs, call service[b].

Note: Patient treatments can be conducted before problem is remedied. The last saved Custom mode values will be used for these treatments.

Possible cause(s):	Service Technician action(s):
Error in saving newly customized values.	Check the Compact Flash Card. If malfunction, replace it.

Ca Syringe Not Loaded

Observation:
This alarm appears during priming only.

Possible cause(s):	Operator action(s):
The calcium syringe is not loaded.	Press the *CHANGE SYR/LINE* to load a calcium syringe. Then press *RETEST* to restart the Syringe Test. If failure recurs, end treatment via *DISCONNECT*. Call service.

Possible cause(s):	Service Technician action(s):
The syringe pump failed.	Check the function of the syringe pump in Diagnose Screen – Syringe Pump on page 6:36. Perform a calibration, see Calibration Screen – Syringe Pump Calibration on page 6:66. If malfunction, replace the syringe pump.

Checksum Interrupted

Possible cause(s):	Operator action(s):
Power loss occurred while internal "checksum" information update was in progress. Some settings might have been lost. Data block in question is identified on the alarm screen.	End treatment via *DISCONNECT* or manually[a], then start a new treatment.

Clamp Stuck Closed

Possible cause(s):	Operator action(s):
External force on return line clamp.	Check return line clamp. Press *RETEST*.
Return line clamp failed.	If alarm does not clear, change set via *CHANGE SET* or end treatment via *DISCONNECT*[a]. Call service.

Possible cause(s):	Service Technician action(s):
Return line clamp failed.	Check the function of the return line clamp in Diagnose Screen – Clamp and Pinch Valves on page 6:41. If malfunction, replace the Return line clamp.

Communication Error

Observation:
Error Code: 2 to 7
Due to:
Code=2 No communication with the protective task
Code=3 Communication link error on the protective slave
Code=4 Communication link error on the control system
Code=5 Missing status command from protective slave
Code=6 Missing alarm command from protective slave
Code=7 The protective task isn't able to send message to the slave

Possible cause(s):	Operator action(s):
See "Due to" message on *alarm* screen.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). Note: Treatment can not resume using the loaded set once blood has been returned. Restart machine. Once *Query* screen appears, make choice and carefully follow instructions. If alarm recurs, end treatment manually (see above). Call service and report failure code before using machine again.

Possible cause(s):	Service Technician action(s):
Code=2 No communication with the protective task Code=3 Communication link error on the protective slave Code=4 Communication link error on the control system Code=5 Missing status command from protective slave Code=6 Missing alarm command from protective slave Code=7 The protective task isn't able to send message to the slave	The codes can appear by themselves or in combination. Use the software CD. If there has been an error in the actual software download or if there is an issue on the I2C bus, this can be shown. Connect a key board and insert the Software CD. Go into the BIOS Menu and verify that the Boot sequence is set to CD ROM, C, A. Exit the BIOS menu. Follow the instruction given on the screen. Make sure all components are correctly connected. Make sure all boards have voltage. If malfunction, replace the component.

Custom Data

Possible cause(s):	Operator action(s):
Not able to access Custom mode values for selected therapy/set.	Discontinue use. If applicable, use *DISCONNECT* to unload/remove set. Turn machine off and call service to remedy and clear the alarm.[b]

Dialysate Pump

Observation:
Rate of dialysate (green) pump is incorrect.

Possible cause(s):	Operator action(s):
Momentary problem with pump roller or pump segment in raceway.	Press *CONTINUE*.
Impeding object, clamped line or kinked line in pump raceway; thumb screw in center of rotor has loosened.	If alarm recurs, end treatment: Press *CONTINUE*. When `Status` screen appears, immediately press *STOP*. On `Stop` screen, choose *END TREATMENT* and follow the instructions to disconnect patient and unload set. Call service to remedy/clear alarm[b].
Clamped line.	Check for clamped line. Press *CONTINUE*
Pump failed.	Call for service.

Possible cause(s):	Service Technician action(s):
Thumb screw in center of rotor has loosened.	Check the screw. Remedy if needed.
Pump failed.	Check the function of the Dialysate pump in Diagnose Screen – Pumps Diagnose on page 6:26. If malfunction, replace the Dialysate pump.

Dialysate Scale Sensor

Observation:
This alarm appears during priming only.

Possible cause(s):	**Operator action(s):**
The bar tray of the dialysate scale has not been pulled out and then pushed into the control unit to attach the dialysate bag.	Place the scale in open position and then in closed position. Press *RETEST*. If this does not clear the alarm, end treatment via *DISCONNECT*. Call service.
The scale position sensor failed.	End treatment via *DISCONNECT*. Call service.

Possible cause(s):	**Service Technician action(s):**
Scale sensor failure.	Check the function of the scale sensor in Diagnose Screen – Scale Diagnose on page 6:28. If scale sensor test fails, replace the scale.
The scale position sensor failed.	See above action.

Effluent Pump

Observation:
Rate of effluent (yellow) pump is incorrect.

Possible cause(s):	**Operator action(s):**
Momentary problem with pump roller or pump segment in raceway.	Press *CONTINUE*.
Impeding object, clamped line or kinked line in pump raceway; thumb screw in center of rotor has loosened.	If alarm recurs, end treatment: Press *CONTINUE*. When `Status` screen appears, immediately press *STOP*. On `Stop` screen, choose *END TREATMENT* and follow the instructions to disconnect patient and unload set. Call service to remedy/clear alarm[b].
Pump failed.	Call for service.

Possible cause(s):	Service Technician action(s):
Thumb screw in center of rotor has loosened.	Check the screw. Remedy if needed.
Pump failed.	Check the function of the Effluent pump in Diagnose Screen – Pumps Diagnose on page 6:26. If malfunction, replace the Effluent pump.

Effluent Scale Sensor

Observation:
This alarm appears during priming only.

Possible cause(s):	Operator action(s):
The bar tray of the effluent scale has not been pulled out and then pushed into the control unit to attach the effluent bag.	Place the scale in open position and then in closed position. Press *RETEST*. If this does not clear the alarm, End treatment via *DISCONNECT*. Call service.
The scale position sensor failed.	End treatment via *DISCONNECT*. Call service.

Possible cause(s):	Service Technician action(s):
Scale sensor failure.	Check the function of the scale sensor in Diagnose Screen – Scale Diagnose on page 6:28. If scale sensor test fails, replace the scale.
The scale position sensor failed.	See above action.

General System Failure

Observation:
Error Code: 1 to 6

Possible cause(s):	Operator action(s):
Turning Fluid pumps or Blood pump when machine in Safe state; Clamp forced to wrong position when machine in Safe state; No communication.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). Note: Treatment can not resume using the loaded set once blood has been returned. Restart machine. Once *Query* screen appears, make choice and carefully follow instructions. If alarm recurs, end treatment manually (see above). Call service and report failure code before using machine again.

Possible cause(s):	Service Technician action(s):
Code 1 Blood pump movement. Code 2 Fluid pump(s) movement. Code 3 Return clamp not closed. Code 4 Criteria_Counter vs Criteria_Exhausted mismatch in Protective Slave. Code 5 I2C error during start-up. Code 6 Syringe Pump movement.	Code 1 Check the function of the Blood pump in Diagnose Screen – Pumps Diagnose on page 6:26. If malfunction, replace the Blood pump. Code 2 Check the function of the pump(s) in Diagnose Screen – Pumps Diagnose on page 6:26. If malfunction, replace the pump(s). Code 3 Check the function of the Return clamp in Diagnose Screen – Clamp and Pinch Valves on page 6:41. If malfunction, replace the Return clamp. Code 4 Check the function of the Hall sensor in Diagnose Screen – Pumps Diagnose on page 6:26. If malfunction, replace the Hall sensor. Code 5 Use the software CD. If there has been an error in the actual software download or if there is an issue on the I2C bus, this can be shown. Connect a key board and insert the Software CD. Go into the BIOS Menu and verify that the Boot sequence is set to CD ROM, C, A. Exit the BIOS menu. Follow the instruction given on the screen.

	Code 6 Check the function of the syringe pump in Diagnose Screen – Syringe Pump on page 6:24. Perform a calibration, see Calibration Screen – Syringe Pump Calibration on page 6:51. If malfunction, replace the syringe pump.

Library Data

Possible cause(s):	Operator action(s):
Cannot access manufacturer-set default values.	Discontinue use. If applicable, use *DISCONNECT* to unload/remove set. Turn machine off and call service to remedy and clear the alarm.[b]

Possible cause(s):	Service Technician action(s):
Cannot access manufacturer-set default values.	Check the Compact Flash Card. If malfunction, replace it.

Line in Air Detector

Possible cause(s):	Operator action(s):
Return line installed in air bubble detector before loading a set.	Remove line from air bubble detector, then close door of air bubble detector. Press *RETEST*. If alarm doesn't clear, turn machine off. Call service.
Tubing detection switch failed.	Turn machine off. Call service.

Possible cause(s):	Service Technician action(s):
Tubing detection switch failed.	Check the function of the Tubing detection switch, see Diagnose Screen – Air Detector on page 6:34. If malfunction, replace the Air detector.

Line in Clamp

Possible cause(s):	Operator action(s):
Return line installed in Return Line Clamp before loading a set.	Remove line from Return Line Clamp. Press *RETEST*. If alarm doesn't clear, turn machine off. Call service.
Tubing detection switch failed.	Turn machine off. Call service

Possible cause(s):	Service Technician action(s):
Tubing detection switch failed.	Check the function of the Tubing detection switch in Diagnose Screen – Clamp and Pinch Valves on page 6:41. If malfunction, replace the Return clamp.

Lower Pinch Valve

Possible cause(s):	Operator action(s):
The lower pinch valve is in the wrong position for the therapy selected and the current infusion method selected (Pre/Post) due to obstructions.	Remove any obstructions and press *RETEST*. If this does not clear the alarm, end treatment via DISCONNECT. Call service.
The lower pinch valve failed.	End treatment via *DISCONNECT*. Call service.

Possible cause(s):	Service Technician action(s):
The lower pinch valve failed.	Check the function of the lower pinch valve in Diagnose Screen – Clamp and Pinch Valves on page 6:41. If malfunction, change the lower pinch valve.

Memory Error

Observation:
Error Code: number 1, 3 – 7
Due to:
Code=1 Memory error on Protective task.

Code=3 Wrong CRC of a set value.
Code=4 Set value incongruence between Protective slave and task.
Code=5 Incongruence on the alarm structure of the control system.
Code=6 Set value incongruence between protective and control.[c]
Code=7 Backup memory

Possible cause(s):	**Operator action(s):**
See "Due to" message on *alarm* screen.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). Note: Treatment can not resume using the loaded set once blood has been returned. Restart machine. Once *Query* screen appears, make choice and carefully follow instructions. If alarm recurs, end treatment manually (see above). Call service and report failure code before using machine again.

Possible cause(s):	**Service Technician action(s):**
Code=1 Memory error on Protective task. Code=3 Wrong CRC of a set value. Code=4 Set value incongruence between Protective slave and task. Code=5 Incongruence on the alarm structure of the control system. Code=6 Set value incongruence between protective and control system. Code=7 Backup memory	Code 1, 3 – 5, 7 Use the Software CD to verify the correct Software CRC on the Protective. Connect a key board and insert the Software CD. Go into the BIOS Menu and verify that the Boot sequence is set to CD ROM, C, A. Exit the BIOS menu. Follow the instruction given on the screen. Code 6 Restart the Prismaflex control unit with the main switch. Reinstall the syringe if needed. Re-enter the fluid flows.

No Line in Air Detector

Possible cause(s):	**Operator action(s):**
Return line not installed or not properly installed in air bubble detector.	Open door of air bubble detector and insert line into air bubble detector. If return line is installed in the air bubble detector, press line into detector from bottom up and route securely through tubing guides. Press *RETEST*. If alarm doesn't clear, end treatment via *DISCONNECT*. Call service.
Tubing detection switch failed.	End treatment via *DISCONNECT*. Call service.

Possible cause(s):	Service Technician action(s):
Tubing detection switch failed.	Check the function of the Tubing detection switch, see Diagnose Screen – Air Detector on page 6:34. If malfunction, replace the Air detector.

No Line in Clamp

Possible cause(s):	Operator action(s):
Return line not installed or not properly installed in Return Line Clamp.	Insert line into the clamp. Press *RETEST*. If alarm doesn't clear, end treatment via *DISCONNECT*. Call service.
Tubing detection switch failed.	End treatment via *DISCONNECT*. Call service.

Possible cause(s):	Service Technician action(s):
Tubing detection switch failed.	Check the function of the Tubing detection switch in Diagnose Screen – Clamp and Pinch Valves on page 6:41. If malfunction, replace the Return clamp.

Normalization Failed

Observation:
Attempt to normalize blood leak detector has failed.

Possible cause(s):	Operator action(s):
Filter blood leak; defective effluent line; air bubble in effluent line at level of BLD; effluent line not correctly installed; blood leak detector failed. Note: The Malfunction: Normalization failed alarm is displayed when the blood leak detector normalization has failed 3 times in a row.	Press *CHANGE SET* and follow the instructions to load a new set. If alarm recurs with new set, detector has failed. Press *DISCONNECT* to end treatment. Call service.

Possible cause(s):	Service Technician action(s):
Blood leak detector failed.	Check the function of the Blood leak detector in Diagnose Screen – BLD (Blood Leak Detector) on page 6:43. If malfunction, replace the Blood leak detector.

PBP Pump

Observation:
Rate of pre-blood (white) pump is incorrect.

Possible cause(s):	Operator action(s):
Momentary problem with pump roller or pump segment in raceway.	Press *CONTINUE*.
Impeding object, clamped line or kinked line in pump raceway; thumb screw in center of rotor has loosened.	If alarm recurs, end treatment: Press *CONTINUE*. When `Status` screen appears, immediately press *STOP*. On `Stop` screen, choose *END TREATMENT* and follow the instructions to disconnect patient and unload set. Call service to remedy/clear alarm[b].
Pump failed.	Call for service.

Possible cause(s):	Service Technician action(s):
Thumb screw in center of rotor has loosened.	Check the screw. Remedy if needed.
Pump failed.	Check the function of the PBP pump in Diagnose Screen – Pumps Diagnose on page 6:26. If malfunction, replace the PBP pump.

PBP Scale Sensor

Observation:
This alarm appears during priming only.

Possible cause(s):	**Operator action(s):**
The bar tray of the PBP scale has not been pulled out and then pushed in the control unit to attach the PBP bag.	Place the scale in open position and then in closed position. Press *RETEST*. If this does not clear the alarm, end treatment via *DISCONNECT*. Call service.
The scale position sensor failed.	End treatment via *DISCONNECT*. Call service.

Possible cause(s):	**Service Technician action(s):**
Scale sensor failure	Check the function of the scale sensor in Diagnose Screen – Scale Diagnose on page 6:28. If scale sensor test fails, replace the scale.
The scale position sensor failed.	See above action.

Pressures Circuit Board

Possible cause(s):	**Operator action(s):**
Hardware failure on pressures circuit board.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). Call service.

Possible cause(s):	**Service Technician action(s):**
Hardware failure on pressures circuit board.	Check the function of the pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. If malfunction, replace the pressures circuit board.

Pressure Zero Test

Observation:
Zero test of one or more pressure sensors failed.

Possible cause(s):	**Operator action(s):**
One or more pressure pods are installed in pressure sensor housings, but should not be installed yet.	If pressure pods are installed in housings, remove them. Press *RETEST*.
One or more pressure sensors failed or are incorrectly calibrated.	If alarm does not clear, turn off machine. Call service.

Possible cause(s):	**Service Technician action(s):**
One or more pressure sensors failed or are incorrectly calibrated.	Check the function of the pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. Perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. If malfunction, change the pressure sensors.

Prime Self-Test

Observation:
Code: 1 to 28.

Detailed information on different alarm codes follows below.

Possible cause(s):	**Operator action(s):**
One or more of the tests conducted during prime self-test failed.	Softkeys on *alarm* screen vary, depending upon failure reason. All softkeys clear the alarm. *DISCONNECT* provides instructions to unload/remove set. *NEW SET* gives instructions to unload set, load a new set, and start a new priming cycle. *REPRIME* provides instructions to reprime the set. *RETEST* restarts the prime test.

Prime Self-Test

Observation:
Code: 1–7.
Due to: Pressure pod/sensor. All affected pods are reported.
Code=1 Access

Code=2 Filter

Code=3 Access and Filter

Code=4 Effluent (CRRT, TPE)

Code=5 Access and Effluent (CRRT, TPE)

Code=6 Filter and Effluent (CRRT, TPE)

Code=7 Access, Effluent and Filter (CRRT, TPE)

Possible cause(s):	**Operator action(s):**
Pressure pod(s) not installed; debris in sensor housing(s); leaking pod.	Install/check that all reported pressure pod(s) on the alarm screen are installed correctly. Press *RETEST*.
Clamped lines in set.	Unclamp any clamped lines. Press *RETEST*.
Pressure sensor(s) failed.	Unload set via *DISCONNECT*. Call service and report failure code.

Possible cause(s):	**Service Technician action(s):**
Pressure sensor(s) failed	Check the function of the ARPS according to point 10, 11 in Diagnose Screen – Pressure Pod Reposition on page 6:30. Check the function of the pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. If deviation, perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. If malfunction, replace the ARPS and/or pressure sensors.

Prime Self-Test

Observation:
Code=16
Due to: Return pressure sensor.

Possible cause(s):	**Operator action(s):**
Clamped lines in set.	Unclamp any clamped lines. Press *RETEST*.
Chamber monitor line not securely connected to return pressure port.	Verify the fluid barrier is not wet/ damaged. If not wet/damaged, secure monitor line to the luer lock of the return pressure port and press *REPRIME* to prime the same set again. If the fluid barrier is wet/damaged, press *DISCONNECT* and use *CHANGE SET* to load/prime a new set.
Pressure sensor(s) failed.	If failure occurs again with a new set, unload set via *DISCONNECT*. Call service and report failure code.
Air in set and bad priming quality.	Press *REPRIME* to prime the set again.

Possible cause(s):	**Service Technician action(s):**
Pressure sensor(s) failed.	Check the function of the ARPS and Return pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. If deviation, perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. If malfunction, replace the ARPS and/or Return pressure sensors.

Prime Self-Test

Observation:
Code=17 and 18
Due to: Blood leak detector normalization timeout or Blood leak detector threshold error.

Possible cause(s):	Operator action(s):
Effluent line not correctly installed in blood leak detector.	Reinstall effluent line (from bottom up); route through tubing guides. Press *RETEST*.
Air bubble in effluent line at level of blood leak detector.	Dislodge bubble by removing line from detector / tapping on tube. Press *RETEST*.
Set not fully primed.	Check for clamped lines and for connections; remedy. Press *REPRIME* and follow instructions. If failure recurs after the above Operator Responses, retry with a new set (Press *NEW SET* and follow instructions.)
Blood leak detector failed.	If failure occurs with the new set, unload set via *DISCONNECT*. Call service and report failure code.
Liquid or debris in tubing path through the detector.	Remove line from detector. Using a "flossing" action, clean inside the detector with a lint-free cloth and isopropyl alcohol. Dry thoroughly. Clean effluent line with water and dry thoroughly. Reinsert line into detector and tubing guides. Press *OVERRIDE*[a].

Possible cause(s):	Service Technician action(s):
Blood leak detector failed.	Check the function of the Blood leak detector in Diagnose Screen – BLD (Blood Leak Detector) on page 6:43. If malfunction, replace the Blood leak detector.

Prime Self-Test

Observation:
Code=19
Due to: Air/pumps security test.

Possible cause(s):	**Operator action(s):**
Internal malfunction.	Press *RETEST*. If failure recurs, unload set via *DISCONNECT*. Call service and report failure code.
Presence of air at ABD level.	Disconnect monitor line and refill the chamber.

Possible cause(s):	**Service Technician action(s):**
Internal malfunction	Check the function of the Air bubble detector in Diagnose Screen – Air Detector on page 6:34. If deviation, perform a calibration. If malfunction, replace the Air bubble detector. Check the function of the pump(s) in Diagnose Screen – Pumps Diagnose on page 6:26. If deviation, replace the pump(s).

Prime Self-Test

Observation:
Code=20
Due to: Pump occlusivity test.

Possible cause(s):	**Operator action(s):**
Return line not properly installed in return line clamp; obstruction in return line clamp.	Press *REPRIME*. Install return line in the released return line clamp and prime the same set again. If failure occurs again, press *DISCONNECT* and use *CHANGE SET* to load/prime a new set.
Deaeration chamber monitor line not connected to return pressure port; errors occurred during priming cycle.	Verify the fluid barrier is not damaged and tighten fluid barrier connection to chamber monitor line. If not damaged, secure monitor line to the luer lock of the return pressure port and press *REPRIME* to prime again the same set. If the fluid barrier is

	damaged, press *DISCONNECT* and use *CHANGE SET* to load/prime a new set.
Pump segments improperly loaded; obstructions in pump raceways; external leakage in set.	Check for leakages and tighten connections. If failure recurs for three times, retry with a new set (Press *NEW SET* and follow instructions.)
Pump(s) failed.	If failure occurs with a new set, unload set via *DISCONNECT*. Call service and report failure code.

Possible cause(s):	**Service Technician action(s):**
Pump(s) failed, return pressure sensor failure or leak in pressure ARPS circuit.	Check the function of the Return, Effluent and Filter pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. Check the pressure sensors and pressure ARPS circuit for leakage. If leakage is detected, remedy the pressure pod sealing cones, the pressure sensor, pressure valves, ARPS pump alt ARPS circuit. Perform a “Verification of slave pump rotor” test, see point 5 in Component Replacement on page 6:17. Check the function of the Blood pump in Diagnose Screen – Pumps Diagnose on page 6:26. If malfunction, replace the Blood pump. Check the function of the Return line clamp in Diagnose Screen – Clamp and Pinch Valves on page 6:41. If malfunction, replace.

Prime Self-Test

Observation:
Code=21 – 23
Due to: Pinch valve(s).

Possible cause(s):	**Operator action(s):**
Pinch valve(s) segment(s) not properly positioned in pinch valve(s).	Press *RETEST*. If failure recurs, retry with a new set (Press *NEW SET* and follow instructions.)

Pinch valve(s) failed.	If failure occurs with a new set, unload set via *DISCONNECT*. Call service and report failure code.

Possible cause(s):	**Service Technician action(s):**
Pinch valve failed.	Check the function of the pinch valves in Diagnose Screen – Clamp and Pinch Valves on page 6:41. If malfunction, replace the pinch valves.

Prime Self-Test

Observation:
Code=24
Due to: 24 volt / 12 volt.

Possible cause(s):	**Operator action(s):**
24 volt / 12 volt test failed.	Press *RETEST*. If failure recurs, unload set via *DISCONNECT*. Call service and report failure code.

Possible cause(s):	**Service Technician action(s):**
24 volt / 12 volt test failed.	Check that the ARPS circuit are connected to each of the pressure sensor valve. Check the function of the ARPS in according to point 10, 11 in Diagnose Screen – Pressure Pod Reposition on page 6:30. If malfunction, replace ARPS pressure sensor alt ARPS pump.

Prime Self-Test

Observation:
Code=25
Due to: Return clamp sensor.

Possible cause(s):	**Operator action(s):**
Obstruction in return line clamp.	Press and hold return clamp button. With the other hand, remove obstruction. Press *RETEST*.

Return clamp sensor failed.	If alarm failure recurs, unload set via *DISCONNECT*. Call service and report failure code.

Possible cause(s):	**Service Technician action(s):**
Return clamp sensor failed.	Check the function of the Return line sensor in Diagnose Screen – Clamp and Pinch Valves on page 6:41. If malfunction, replace the Return clamp sensor.

Prime Self-Test

Observation:
Code=26
Due to: 24 volt Return clamp sensor.

Possible cause(s):	**Operator action(s):**
24 volt and return clamp sensor tests failed.	Press *RETEST*. If failure recurs, unload set via *DISCONNECT*. Call service and report failure code.

Possible cause(s):	**Service Technician action(s):**
24 volt and return clamp sensor tests failed.	Check that the ARPS circuit are connected to each of the pressure sensor valve. Check the function of the ARPS in according to point 10, 11 in Diagnose Screen – Pressure Pod Reposition on page 6:30. If malfunction, replace ARPS pressure sensor alt ARPS pump. Check the function of the Return line sensor in Diagnose Screen – Clamp and Pinch Valves on page 6:41. If malfunction, replace the Return clamp sensor.

Prime Self-Test

Observation:
Code=27
Due to: TMPa.

Possible cause(s):	Operator action(s):
Return line not in clamp.	Ensure chamber monitor line is securely connected to luer lock of the return pressure port. Press *RETEST*.
Filter or effluent pressure pod not installed; debris in filter and/or effluent sensor housings.	Install/check that all reported pressure pod(s) on the alarm screen are installed correctly. Press *RETEST*.
Set not fully primed.	Press *REPRIME*, follow instructions. If failure recurs, retry with new set. (Press *NEW SET* and follow instructions.)
Filter, effluent, or return pressure sensor failed; ARPS failed.	If alarm occurs with a new set, press unload set via *DISCONNECT*. Call service and report failure code.

Possible cause(s):	Service Technician action(s):
Filter, effluent, or return pressure sensor failed; ARPS failed.	Check the function of the ARPS according to point 10, 11 in Diagnose Screen – Pressure Pod Reposition on page 6:30. Check the function of the pressure sensors in Diagnose Screen – Pressure Pod Reposition on page 6:30. If deviation, perform a calibration, see Calibration Screen – Pressure Sensors Calibration on page 6:64. If malfunction, replace the ARPS and/or pressure sensors.

Prime Self-Test

Observation:
Code=28
Due to: Syringe Pump HW.

Possible cause(s):	Operator action(s):
Internal malfunction: syringe test not completed within 600 s.	Press *RETEST* to restart Syringe Test. . If failure recurs, press *DISCONNECT*, call service and report failure code number.

Replacement Pump

Observation:
Rate of replacement (purple) pump is incorrect.

Possible cause(s):	Operator action(s):
Momentary problem with pump roller or pump segment in raceway.	Press *CONTINUE*.
Impeding object, clamped line or kinked line in pump raceway; thumb screw in center of rotor has loosened.	If alarm recurs, end treatment: Press *CONTINUE*. When `Status` screen appears, immediately press *STOP*. On `Stop` screen, choose *END TREATMENT* and follow the instructions to disconnect patient and unload set. Call service to remedy/clear alarm[b].
Pump failed.	Call for service.

Possible cause(s):	Service Technician action(s):
Thumb screw in center of rotor has loosened.	Check the screw. Remedy if needed.
Pump failed.	Check the function of the Replacement pump in Diagnose Screen – Pumps Diagnose on page 6:26. If malfunction, replace the Replacement pump.

Replacement Pump 2

Observation:
Rate of replacement 2 (green) pump is incorrect.

Possible cause(s):	**Operator action(s):**
Momentary problem with pump roller or pump segment in raceway.	Press *CONTINUE*.
Impeding object, clamped line or kinked line in pump raceway; thumb screw in center of rotor has loosened.	If alarm recurs, end treatment: Press *CONTINUE*. When `Status` screen appears, immediately press *STOP*. On `Stop` screen, choose *END TREATMENT* and follow the instructions to disconnect patient and unload set. Call service to remedy/clear alarm[b].
Pump failed.	Call for service.

Possible cause(s):	**Service Technician action(s):**
Thumb screw in center of rotor has loosened.	Check the screw. Remedy if needed.
Pump failed.	Check the function of the Replacement 2 pump in Diagnose Screen – Pumps Diagnose on page 6:26. If malfunction, replace the Replacement 2 pump.

Replacement Scale Sensor

Observation:
This alarm appears during priming only.

Possible cause(s):	**Operator action(s):**
The bar tray of the replacement scale has not been pulled out and then pushed into the control unit to attach the replacement bag.	Place the scale in open position and then in closed position. Press *RETEST*. If this does not clear the alarm, end treatment via *DISCONNECT*. Call service.
The scale position sensor failed.	End treatment via *DISCONNECT*. Call service.

Possible cause(s):	**Service Technician action(s):**
Scale sensor failure.	Check the function of the scale sensor in Diagnose Screen – Scale Diagnose on page 6:28. If scale sensor test fails, replace the scale.
The scale position sensor failed.	See above action.

Scales

Observation:
Scale in question is specified on the *alarm* screen.

Possible cause(s):	**Operator action(s):**
Specified scale is out of calibration.	Press *RETEST*. If alarm does not clear, end treatment via *DISCONNECT*[d]. Turn machine off, remove return line from return line clamp, and return blood (when applicable). Call service.

Possible cause(s):	**Service Technician action(s):**
Specified scale is out of calibration.	Calibrate the scale, see Calibration Screen – Scales Calibration on page 6:61. Verify the function of the scale in Diagnose Screen – Scale Diagnose on page 6:28. If deviation, replace the scale.

Scales Circuit Board

Possible cause(s):	**Operator action(s):**
Hardware failure on scales circuit board.	End treatment via *DISCONNECT*. Call service.

Possible cause(s):	**Service Technician action(s):**
Hardware failure on scales circuit board.	Check the function of the scale in Diagnose Screen – Scale Diagnose on page 6:28. If malfunction, replace the scale.

Scale Zero Test

Observation:
Zero test of one or more scales failed.

Possible cause(s):	**Operator action(s):**
Unexpected presence of bag.	Remove bag from scale. Close scale and press *RETEST*.
Carrying bar missing from one or more scales.	Place carrying bar back on scale. Close scale and press *RETEST*.
Foreign objects are touching scales or hanging from scale carrying bars.	Make sure nothing is touching scales and no foreign objects are on scale carrying bars. Press *RETEST*.
One or more scales failed.	If alarm does not clear, turn off machine. Call service.

Possible cause(s):	**Service Technician action(s):**
One or more scales failed.	Check the function of the scales in Diagnose Screen – Scale Diagnose on page 6:28. If needed, calibrate the scales, see Calibration Screen – Scales Calibration on page 6:61. Run the Prismaflex control unit again, perform a new Prime. If the alarm recurs, replace the scale(s).

Self-Test Failure

Observation:
For **Possible cause(s)** and **Operators action(s)**,
see correspondent code for Prime Self-Test Alarm.
Code=1–7, Pressure pod/sensor
Code=16, Return pressure sensor
Code=18, Blood leak detector threshold error
Code=24, 24 volt / 12 volt
Code=25, Return clamp sensor
Code=26, 24 volt Return clamp sensor

WARNING

The blood leak detector must be re-normalized if the effluent line is removed and then reinserted into the blood leak detector after treatment (Run mode) has started.

WARNING

Syringe Not Loaded

Possible cause(s):	**Operator action(s):**
The syringe is not loaded after Syringe Test has been performed.	- Press *CHANGE SYRINGE*, follow instructions to load the syringe and return to *alarm* screen. - Press *RETEST* to restart Syringe Test. - If failure recurs, press *DISCONNECT*, call service and report failure.

Possible cause(s):	**Service Technician action(s):**
The syringe pump failed.	Check the function of the syringe pump in Diagnose Screen – Syringe Pump on page 6:36. Perform a calibration, see Calibration Screen – Syringe Pump Calibration on page 6:66. If malfunction, replace the syringe pump.

Syringe Pump

Observation:
Code: 1–9.
Code = 1 Working mode incongruence between Syringe pump and set mode.
Code = 2 Rate is incorrect.
Code = 3 Syringe pump is moving in the wrong direction.
Code = 4 Configuration incongruence between Syringe pump and the system / wrong version of firmware.
Code = 5 Lower sensor out of order.
Code = 6 Maximum of load sensor / unable to read force (short circuit).
Code = 7 Minimum of load sensor / unable to read force (grounded).
Code = 8 Working mode incongruence between Syringe pump and Control unit.
Code = 9 Encoder signal error / engine mechanically blocked.

Possible cause(s):	Operator action(s):
Syringe pump failed.	Press *OVERRIDE*[e]. The syringe pump test will restart after 60 seconds. For "Systemic, Prismaflex syringe pump" method: if alarm recurs, it is possible to continue without using the syringe pump, if desired. To do this, press *ANTICOAG SETTINGS* and set the syringe pump delivery to "Continuous, 0 ml/h." Return to *alarm* screen and press *OVERRIDE*[e] or turn machine off, remove return line from return line clamp, and return blood (when applicable). Call service.

For "Citrate – Calcium, Prismaflex syringe pump" method: if alarm recurs, it is not possible to proceed. Press *END TREATMENT* and follow the instructions on the screen.

Note: Always call service to repair the syringe pump and clear the alarm.

Possible cause(s):	Service Technician action(s):
Syringe pump failed.	Check the function of the syringe pump in Diagnose Screen – Syringe Pump on page 6:36. Perform a calibration, see Calibration Screen – Syringe Pump Calibration on page 6:66. If malfunction, replace the syringe pump.

Upper Pinch Valve

Possible cause(s):	Operator action(s):
The upper pinch valve is in the wrong position for the therapy selected due to obstructions.	Remove any obstructions and press *RETEST*. If this does not clear the alarm, end treatment via DISCONNECT. Call service.
Pinch valve(s) failed.	End treatment via *DISCONNECT*. Call service.

Possible cause(s):	Service Technician action(s):
Upper pinch valve failed.	Check the function of the lower pinch valve in Diagnose Screen – Clamp and Pinch Valves on page 6:41. If malfunction, change the lower pinch valve.

Voltage Out of Range

Possible cause(s):	Operator action(s):
Internal malfunction related to the machine Power Supply or the Power supply cabling.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). Call service.

Possible cause(s):	Service Technician action(s):
Internal malfunction related to the Prismaflex control unit Power Supply or the Power supply cabling.	Perform power supply check, see Power Supply Check on page 6:20. If deviation, replace the power supply. Check the function of the Blood pump in Diagnose Screen – Pumps Diagnose on page 6:26. If malfunction, replace the Blood pump.

Footnotes

a. Manual termination instructions are provided at the end of the Troubleshooting chapter in the Operator's manual for Prismaflex.
b. This alarm must be cleared in Service mode by an authorized service technician.
c. Memory Error code 6 is triggered when Flow Rate Discrepancy occurs. A Flow Rate Discrepancy is when any flow rate displayed on the *Status* screen differs from that displayed on the `Enter Flow Settings` Screen.
d. DISCONNECT key is available only if set is loaded onto control unit.
e. OVERRIDE briefly overrides the alarm. Monitor closely.

Miscellaneous

Display Error

Observation:
Display goes blank, status lights go off, non-mutable buzzer sounds.

Possible cause(s):	**Operator action(s):**
Power loss, internal power supply failure.	Turn off machine to stop buzzer, end treatment manually, if desired[a].

Display Error

Observation:
Display goes blank momentarily, then screen reappears.

Possible cause(s):	**Operator action(s):**
Power was lost and restored within 15 seconds.	None required.

Display Error

Observation:
Display goes blank or logo screen fails to leave display, status lights may still be on, no buzzer.

Possible cause(s):	**Operator action(s):**
Internal power supply failure; internal malfunction.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). Call service.

Possible cause(s):	**Service Technician action(s):**
Internal power supply failure; internal malfunction.	Check the voltage on the boards. Check function of the PC 104 board. Check the connections between the PC 104 board and the display.

Display Error

Observation:
Display “floats around”

Possible cause(s):	Operator action(s):
Display failure.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). Call service.

Possible cause(s):	Service Technician action(s):
Display failure.	Calibrate the display. See section “Calibrate the display” on page 2:12.

Loader

Observation:
Loader is already in loaded position, so that a set cannot be loaded.

Possible cause(s):	Operator action(s):
Last set was manually disconnected.	Begin normal Setup procedure. When `Load Set` screen appears, press *LOAD*. Press *STOP* in `Loading pumps, please wait` screen, then press *UNLOAD*. When `Load set` screen reappears after `Unloading pumps, please wait` screen, follow online instructions to load the set.

Mis-colored Effluent bag

Observation:
Effluent bag is tinged pink or red.

Possible cause(s):	**Operator action(s):**
Patient's disease state.	Discoloration may indicate removed free hemoglobin, rather than a blood leak in the filter membrane. Press *OVERRIDE* and send effluent sample to blood lab for a cell count. If the result confirms blood cell presence, change the set via *STOP*[b].
Effluent contains red blood cells, but level is below blood leak detection limit.	Send effluent sample to laboratory for analysis. If red blood cells are present, change the set via *STOP*[b].
Hemolysis is occurring due to occlusion.	Verify that the correct clamps are open for the therapy in use, especially for the access line (red) and return line (blue). Verify there are no kinks in the access and return lines. If hemolysis continues, change the set via the STOP key[b].
Hemolysis is occurring during TPE therapy.	Press *STOP* and change set.

Set Connections

Observation:
Leakage from set connections.

Possible cause(s):	**Operator action(s):**
Connections are loose.	Tighten the connections. If leakage continues, change the set via STOP key[b].

Softkeys

Observation:
Softkeys won’t work.

Possible cause(s):	Operator action(s):
Touchscreen failed.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). Call service.

Possible cause(s):	Service Technician action(s):
Touch screen failed.	See actions in Display error-Calibrate the display.

Footnotes

a. Manual termination instructions are provided in the operator’s manual.
b. See “Change Set and End Treatment Procedures” in “End Mode” in the operator’s manual.

Power Failure

The Prismaflex control unit is designed to support the operator during loss of line power or in case the power cord needs to be temporarily unplugged during operation. The way the control unit handles such situations depends on the availability of an additional back-up battery in the control unit, which is available as an accessory.

Note: Line power is required to start the Prismaflex control unit, even if equipped with a back-up battery.

- If a back-up battery is installed, the treatment will proceed during a power failure. The Advisory: Main Power Lost alarm will appear and a battery icon will be visible at the top of the `Status` screen. Once the battery is nearly depleted, the Warning: Battery Low alarm indicates that the treatment must be ended. Instructions how to do so are provided on the alarm screen.

- If a back-up battery is not installed, the treatment will be suspended once line power is lost. Should power be restored within 15 seconds, the treatment will resume. Otherwise, the Warning: Power Failure alarm will appear on the screen and provide recovery instructions.

See also Advisory: Battery Exhausted and Advisory: Memory Back-up for more information.

This page is intentionally left blank

Chapter 6
Maintenance

Contents

About this Chapter 6:3
Electrical Safety Inspection 6:4
General 6:4
Visual inspection 6:5
PET - Protective Earth Test 6:5
Note: 6:5
Test equipment 6:5
Test 6:5
Check of Conductivity Clip 6:6
Test equipment 6:6
Test 6:6
ELT / PLT 6:6
Test equipment 6:6
General conditions for ELT / PLT 6:6
ELT - Earth Leakage Current Test 6:7
PLT - Patient Leakage Current Test 6:8
Test 6:8
Record of Electrical Safety Inspection 6:9
Visual inspection 6:9
Remarks: 6:9
Conductivity Clip Test 6:9
PET - Protective Earth Test 6:10
ELT - Earth Lekage Current Test 6:10
PLT-Patient Leakage Current Test 6:11
Component replacement with needed ESI 6:12
Preventive Maintenance 6:13
Tools Needed 6:13
Working Time 6:14
Prismaflex® PM Kit 6:14
Visual Inspection and Cleaning 6:15
Component Replacement 6:17
Power Supply Check 6:20
Exchange of Lead Batteries for Battery Backup 6:20
Service Mode - Checkout using Service Diagnose Mode 6:21
Service Screens 6:22
Service - Diagnose Screens 6:24
Diagnose Screen – Pumps Diagnose 6:26
Diagnose Screen – Scale Diagnose 6:28
Diagnose Screen – Pressure Pod Reposition 6:30
Diagnose Screen – Alarms Tone and Light 6:32
Diagnose Screen – Air Detector 6:34
Diagnose Screen – Syringe Pump 6:36
Diagnose Screen – Clamp and Pinch Valves 6:41
Diagnose Screen – BLD (Blood Leak Detector) 6:43
Diagnose Screen – Internal 6:44
Diagnose Screen – Communication 6:45
Diagnose Screen – PM timer and Date 6:53
Diagnose Screen – Clean Screen 6:55

Diagnose Screen – SW Configuration 6:56
Diagnose Screen – 2D Barcode 6:57
Service Calibration Screens 6:58
Calibration Screen – Language Configuration 6:60
Calibration Screen – Scales Calibration 6:61
Calibration Screen – Pressure Sensors Calibration 6:64
Calibration Screen – Syringe Pump Calibration 6:66
Calibration Screen – Filter Clotting Limits 6:68
Calibration Screen – Set Clock and Date 6:69
Calibration Screen – Screen Brightness Calibration 6:70
Calibration Screen – Pitch and Volume 6:71
Calibration Screen – External Communication Interface 6:72
Calibration Screen – Therapy/Sets Configuration 6:73
Calibration Screen – Anticoagulation Configuration 6:76
Calibration Screen – Anticoagulation Solutions 6:78
Calibration Screen – Serial Number 6:84
Calibration Screen – Air Detector 6:85
Calibration Screen – IP Settings 6:86
Calibration Screen – Syringe Holder Configuration 6:87
Calibration Screen – Supplementary Syringe 6:88
Calibration Screen – Settings Handling 6:90
Calibration Screen – Blood Warmer Configuration 6:92
Functional Test 6:94
Final Check 6:97

About this Chapter

This chapter provides information regarding maintenance of the Prismaflex control unit. Chapter is divided in the Preventive maintenance, Electrical safety inspection, Diagnose and Calibration of the Prismaflex control unit.

Electrical Safety Inspection

General

To ensure proper operation, a qualified service technician shall perform an Electrical Safety Inspection (ESI) of the Prismaflex control unit at regular intervals. ESI should be performed at every maintenance service (Base-service), but also after replacement of some components in the Prismaflex control unit according to section “Component replacement with needed ESI” on page 6:12. Additionally if the equipment has been exposed to unexpected electrical events on the main supply or unintentional ingress of fluid has occurred, a full Electrical Safety Inspection shall be performed. The information needed to perform ESI is provided in this instruction.

Included in the ESI procedures are checks to verify normal machine operation. Should the Prismaflex control unit fail to pass any of these sub-tests, repair or calibration might be needed, then repeat the tests until the specifications are met.

Following sub-tests are included in the ESI of the Prismaflex control unit:

- Visual inspection
- PET - Protective earth test
- Check of Conductivity Clip
- ELT - Earth leakage current test
- PLT - Patient leakage current test

To avoid premature aging of isolation material no insulation test shall be performed during ESI. Spare parts dependent on insulation are tested at manufacturing and therefore no further test shall be performed with high voltage.

During the visual inspection of the equipment, the service engineer shall look for potential faults related to the electrical safety of the Prismaflex control unit.

The purpose of the PET test is to verify that the protective earthed parts of the control unit are properly connected to protective earth, providing a safe low electrical potential on these in case of insulation failure.

The purposes of the ELT/PLT tests are to verify that non-functional leakage currents to operator and patient are within safe limits.

When performing the ESI, which requires access to the interior of the control unit, you must have proper electrostatic safety devices (i.e. wrist grounding straps or grounding mats) in place to prevent damage to electrostatic sensitive components within the control unit.

Record sheet for each sub-test are included in the end of this instruction. The purpose of these records is to document the work done and to trend the readings from the tests.

Note:
- If the Prismaflex control unit is tested according to IEC 60601-1 (IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance), this complies with requirements in IEC 62353 (IEC 62353: Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment).

Visual inspection

The visual inspection is an important part of the elctrical safety inspections of the Prismaflex control unit.

The visual inspection is a procedure to make sure that the medical equipment in use still confirms the specifications and has not suffered from any external damage and/or contamination.

The visual inspection includes following steps:

1. Exterior parts including covers: look for major damage, cracks etc.

2. Cabling: look for cuts, wrong connections etc.

3. Markings and labelling: check the integrity.

4. Integrity of mechanical parts: check for any visual obstructions.

5. Determine classification of the Prismaflex control unit (BF or CF). Can be found on the type plate on rear panel.

PET - Protective Earth Test

Note:
- The Prismaflex control unit shall not be connected to mains power during this test.

- Limit values for PET-test according to IEC 62353.

Test equipment
Safety tester according to IEC 62353.

Test
1. Check that the resistance between the protective earth connection of the mains plug and the earth connector at the bottom plate where the scales are attached is ≤ 300 mΩ.

2. Check that the resistance between the protective earth connection of the mains plug and the earth connector at the PCB holder at the door is ≤ 300 mΩ.

3. Check that the resistance between the protective earth connection of the mains plug and the earth connector at the ARPS pump is ≤ 300 mΩ.

4. Check that the resistance between the protective earth connection of the mains plug and the earth connector for potential equalization is ≤ 300 mΩ.

Check of Conductivity Clip

Test equipment

Multimeter capable of measuring resistance of 10 MΩ or more with ±2 % accuracy.

Test

1. Start the Prismaflex control unit, let it pass initialization test and be in Setup mode.

2. Measure the resistance between the conductivity clip and the connector for potential equalization with the multimeter.

3. Check that the resistance is:

   1.1 MΩ ± 0.2 MΩ for type BF applied part.

   3.24 MΩ ± 0.15 MΩ for type CF applied part.

ELT / PLT

Test equipment

A safety tester set to measure according to IEC 60601–1.

General conditions for ELT / PLT

1. Connect the Prismaflex control unit to the outlet supply of the safety tester. Use a mains plug adapter for respective mains plug.

2. Measure the supply voltage with the safety tester and register the value in Record of ESI - Machine identification - Supply voltage - Measured.

3. Connect conductivity clip on the Prismaflex control unit via access point and Applied Part jack on the tester.

Note:
To avoid damages on the safety tester, follow the user manual for the safety tester.

4. No other external equipment than specified in this instruction should be connected to the Prismaflex control unit.

5. The protective earth of the Prismaflex control unit must not be in contact with any external protective earth.

6. No potential equalization cable shall be connected during test.

ELT - Earth Leakage Current Test

1. Start the Prismaflex control unit, let it pass initialization test and be in Setup mode.

2. Measure the earth leakage current, Normal Condition, with the safety tester by running Earth Leakage Current test. Test also with reversed polarity of supply voltage.

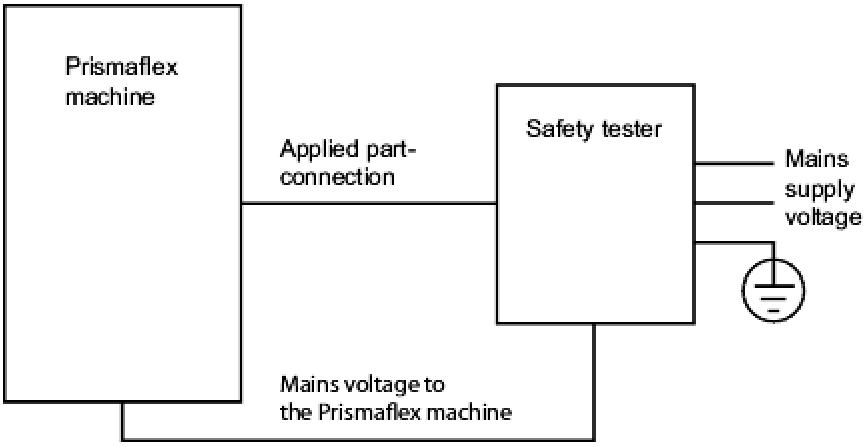
3. Measure the earth leakage current, Single Fault Condition, with the safety tester by running Earth Leakage Current test. Test also with reversed polarity of supply voltage.

4. Check that the highest measured readings don’t exceed the limit values in following table:

Limit values for ELT	
Prismaflex BF or CF, 230 VAC, Normal Condition	Max 500 μA
Prismaflex BF or CF, 230 VAC, Single Fault Condition	Max 1000 μA
Prismaflex BF or CF, 115 VAC, Normal Condition	Max 250 μA
Prismaflex BF or CF, 115 VAC, Single Fault Condition	Max 500 μA

PLT - Patient Leakage Current Test

Use conductivity clip via any reliable connection of the testers probe to the clip as PLT access point.



Test

1. Start the Prismaflex control unit, let it pass initialization test and be in Setup mode.

2. Measure the patient leakage current, Normal Condition, with the safety tester by running Patient Leakage Current test. Test also reversed polarity of supply voltage.

3. Measure the patient leakage current, Single Fault Condition, with the safety tester by running Patient Leakage Current test. Test also reversed polarity of supply voltage.

4. Check that the highest measured readings don't exceed the limit values in following table:

Limit values for PLT	
Prismaflex CF, 230 VAC, Normal Condition	Max 10 µA DC, max 10 µA AC
Prismaflex CF, 230 VAC, Single Fault Condition	Max 50 µA DC, max 50 µA AC
Prismaflex CF, 115 VAC, Normal Condition	Max 10 µA DC, max 10 µA AC
Prismaflex CF, 115 VAC, Single Fault Condition	Max 50 µA DC, max 50 µA AC
Prismaflex BF, 230 VAC, Normal Condition	Max 10 µA DC, max 100 µA AC
Prismaflex BF, 230 VAC, Single Fault Condition	Max 50 µA DC, max 500 µA AC
Prismaflex BF, 115 VAC, Normal Condition	Max 10 µA DC, max 100 µA AC
Prismaflex BF, 115 VAC, Single fault Condition	Max 50 µA DC, max 500 µA AC

Record of Electrical Safety Inspection

Machine identification		
Product code		
Serial number		
Run time (h)		
Classification (BF/CF)		
Supply voltage	_________VAC (nominal)	_________VAC (measured)

Visual inspection

Description	**Approved check**
A visual inspection of the Prismaflex-machine has been performed without any remarks, according to the specified step instruction in section "Visual inspection".	☐

Remarks:

___

___

___

Conductivity Clip Test

Description	**Measured value**	**Approved check**
Check that the resistance between the conductivity clip and the connector for potential equalization is according to section Check of Conductivity Clip, in this chapter. (Limit value type BF applied part: 1.1 MΩ ± 0.2 MΩ) (Limit value type CF applied part: 3.24 MΩ ± 0.15 MΩ)	Applied part: __________ ____________ MΩ	☐

PET - Protective Earth Test

Check no	Description	Measured value	Approved check
1	Check that the resistance between the protective earth connection of the mains plug and the earth connector at the bottom plate where the scales are attached is ≤ 300 mΩ.	________mΩ	☐
2	Check that the resistance between the protective earth connection of the mains plug and the earth connector at the PCB holder at the door is ≤ 300 mΩ.	_________mΩ	☐
3	Check that the resistance between the protective earth connection of the mains plug and the earth connector at the ARPS pump is ≤ 300 mΩ.	_________mΩ	☐
4	Check that the resistance between the protective earth connection of the mains plug and the earth connector for potential equalization is ≤ 300 mΩ.	_________mΩ	☐

ELT - Earth Lekage Current Test

Description	Measured value	Approved check
File the highest measured earth leakage current, normal condition reading according to section ELT-Earth Leakage Current Test, in this chapter: (Limit value 230 VAC: max 500 µA) (Limit value 115 VAC: max 250 µA)	_________ µA	☐
File the highest measured earth leakage, single fault condition reading according to section ELT-Earth Leakage Current Test, in this chapter: (Limit value 230 VAC: max 1000 µA) (Limit value 115 VAC: max 500 µA)	_________ µA	☐

PLT-Patient Leakage Current Test

Description	Measured value	Approved check
File the highest measured patient leakage current, normal condition reading according to section PLT-Patient Leakage Current Test, in this chapter: (Limit value CF, 115 or 230 VAC: max 10 µA DC, max 10 µA AC) (Limit value BF, 115 or 230 VAC: max 10 µA DC, max 100 µA AC)	__________ µA DC __________ µA AC	☐
File the highest measured patient leakage current, single fault condition reading according to section PLT-Patient leakage Current Test, in this chapter: (Limit value CF, 115 or 230 VAC: max 50 µA DC, max 50 µA AC (Limit value BF, 115 or 230 VAC: max 50 µA DC, max 500 µA AC)	__________ µA DC __________µA AC	☐

Compare with the measured leakage currents at the last ESI[1] and make a judgment if the changes are approved or not for the next operational period of the machine. Write notes here:

____

____

____

This record is to be signed and filed by the service engineer responsible for the electrical safety inspection.

Name of testing organization ____________________	Date ____________________
Name of testing service engineer ____________________	Signature ____________________

[1] If this is the ESI at installation please make comparison with the "Production Summary" measured values supplied by the manufacturer at delivery of the Prismaflex control unit.

Component replacement with needed ESI

If one or several of following components are changed, an ESI shall be performed to ensure proper function of the Prismaflex system:

- Power Supply
- Main Switch
- Display
- Pinch Valves
- Venous Clamp
- Speaker & Fan Assembly
- Bar Code Reader
- Loader Motor
- Slave Pump Bracket
- Blood Pump
- Scale Plate
- ARPS Pump
- Syringe Pump

These components has a direct contact with the protective earth.

Preventive Maintenance

The Preventive Maintenance (PM) for the Prismaflex control unit should be performed on a regular basis. PM is required every 6000 hours of operation or once per year whichever occurs first. Upcoming as well as overdue maintenance procedures are signalled to the operator through a reminder screen at the startup of the control unit. Always refer to alarms and troubleshooting in the Service manual related to the actual software revision for details. Only authorized service technicians are allowed to perform preventive maintenance.

Complete the PM checklist (SPI) as the tests are performed.

PM kit always contains latest version of instruction and checklist.

CAUTION

Make sure to have proper electrostatic safety device (i.e. wrist grounding straps or grounding mats) in place to prevent damage to electrostatic sensitive components inside the Prismaflex control unit.

CAUTION

Tools Needed

- Torx T-20
- Torx T-15
- 8 mm Hex
- Flat blade screwdriver
- Pair of long nose pliers
- PC (Personal Computer)
- Prismaflex calibration weights
- Effluent line from a Prismaflex disposable set
- Return line from a Prismaflex disposable set
- Digital Multi Meter (DMM), calibrated
- Current leakage/ground resistance tester, calibrated
- 20, 30 or 50 ml luerlock syringe
- Pressure meter, calibrated
- Pressure calibration tube, or similar
- Prismaflex disposable set

- Catheter (8F) for achieving a simulated treatment with correct pressures.
- 4 fluid bags (saline or equal) of minimum 1000 ml each.
- Stopwatch
- ESI equipment, calibrated

Note: Do not to use power screwdrivers or drills when mounting internal components anywhere on the control unit. Damage to standoffs and/or other plastic components is likely.

Working Time

- Replacement: 30 minutes
- Final check: 90 minutes

Prismaflex® PM Kit

- Blood pump dampers, 2 pcs
- Slave Pump dampers, 8 pcs
- Pressure pod sealing cones, 4 pcs
- Battery for PC 104 board
- ARPS pump segment, 1 pce
- 130 Micron air filter, 1 pce
- PM procedure, 1 pce
- PM checklist, 1 pce
- PM sticker (Next Preventive Maintenance) 2 pcs

Visual Inspection and Cleaning

1. Disconnect the Prismaflex control unit's power cord from the wall socket.

2. Open the rear panel using the 8 mm Hex tool.

3. Clean any dust, debris, and/or dried fluids from the external and internal Prismaflex control unit surfaces, including the fan outlet, rear panel inlet, bottom plate (covering the scales) and pump rotors.

Note: Clean spills from the surface of the Prismaflex control unit using a mild detergent (Never use detergents with germicides).

4. The tubing path through the blood leak detector should be cleaned as required to remove liquid or other debris. Using a flossing action, clean inside the detector with a lint-free cloth and 70% isopropyl alcohol. Dry thoroughly when finished.

5. Verify the proper operation of all wheels and brakes.

6. Verify that there are no mechanical obstructions around the scale hooks and handles.

7. Inspect the Prismaflex control unit for the following and replace as necessary:

   - Cracked pressure sensor housings
   - ARPS tube set, check for kinks, short or damaged tubes
   - Broken tubing guides
   - Filter set holder
   - ABD, including Door
   - Return line clamp
   - Pinch valve, including Pinch pins
   - Damaged syringe pump components
   - Damaged power cord or plug
   - Loose internal electrical connectors

CAUTION

! Do not use sodium hypochlorite (Bleach®) to clean the pump crank. Use of sodium hypochlorite (Bleach®) on this component may damage it.
To clean the touch screen use the following disinfectants: Isopropyl alcohol (70°) Sodium hypochlorite solution (active chlorine from 50,000 to 60,000 ppm)/Bleach diluted with water at a ratio of 1:50.

CAUTION

In the event of a blood leakage from a pod diaphragm or if blood has reached the membrane of the return fluid barrier, following the instructions below:

Blood leakage from the pressure pod diaphragm (Access and Filter)

1. Clean the external surface involved using a towel dipped in a disinfectant solution.

2. Replace the involved pressure sensor assembly(ies) and visually inspect for blood residuals. If blood residuals are present, replace the Pressure Pod Assembly.

3. Test the Prismaflex control unit.

Blood reached the Return fluid barrier

See the Operator's Manual, section Fluid Barrier Related Procedures.

If Blood/infusion solution has passed through the fluid barrier and reached the return pressure port, follow instructions below:

1. Clean the external surface involved using a towel dipped in a disinfectant solution.

2. Replace the Return Pressure Pod Assembly

3. Test the Prismaflex control unit.

Component Replacement

1. **PC 104 Board Battery**

    1.1. Make sure that the Prismaflex control unit is switched off.

    1.2. Open the rear panel using an 8 mm Hex key.

    1.3. Loosen the Torx screw (T-20) holding the plate where the PIB board is mounted.

    1.4. Swing out the bracket where the PIB board is mounted to access the PC board.

    1.5. Push the mental retaining tab outward and remove the battery from its socket.

    1.6. Insert the new battery onto the board (ensure that the + polarity side of the battery faces outward).

2. **Replace the Pressure Pod Sealing Cones (4 cones)**

    2.1. Remove the sealing cone from each transducer port (access, filter, effluent and 5th).

    2.2. Visual inspection of all pressure transducer protectors for traces of blood, clean if needed.

    2.3. Install new sealing cones so that they are sealed around the tip of the transducers, with the enlarged part of the transducer port protruding through the seal. Never use lubricant!

3. **Replace the dampers in the Blood Pump Rotor**

    3.1. Use a T-20 to remove the Blood Pump Rotor.

    3.2. Replace the two dampers on the Rotor and reinstall it on the Prismaflex control unit.

4. **Replace the dampers on the Slave Pump Rotor**

    4.1. Use a flat blade screw driver to remove the Slave pump Rotor.

    4.2. Compress the rotor by hand and use a pair of long nose pliers to remove the old dampers.

    4.3. Compress the rotor and push the new dampers over the screw head with your fingers.
    Note: Do not adjust the screws.

    4.4. Remount the rotor

    4.5. Continue from step 1 until all rotors has been updated.

5. **Emptying the Technical Data Card**

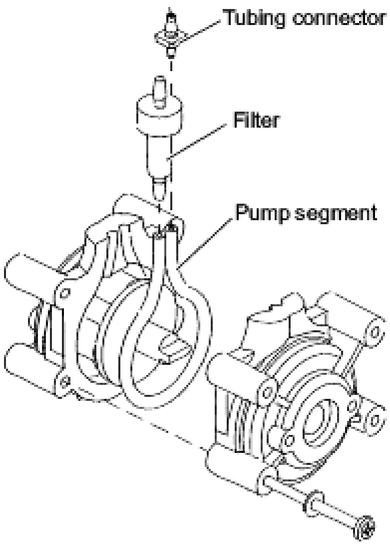
5.1. Exchange the card or download the data on the technical data card to a PC. Check with local personnel if the data is needed.

5.2. Erase the content of the card and put it back into the Prismaflex control unit.

6. **Automatic Reposition System Filter and Pump Segment**

6.1. Loosen the four Torx screws (T-20) on the back of the ARPS pump housing and remove the pump assembly.

6.2. Separate the two halves of the pump and remove the old pump segment.



6.3. Remove the tubing connector from the pump segment. Save the tubing connector for use on the new pump segment. Dispose the filter and pump segment.

6.4. Install the new pump segment by carefully working it under each of the rollers in one-half of the housing assembly. Re-assemble the pump housing halves. The segment should be centred in the housing assembly.

6.5. Ensure that the female slot of the ARPS pump assembly lines up properly with the male slot on the ARPS motor collar. Secure the pump housing assembly to the ARPS bracket with the four screws.

Note: Start the four screws by hand. Make sure the threads on the screws grip properly before applying any force on to the screw.

6.6. Reconnect the tubing connector (removed in step 3) and install the new filter on the pump segment so that the filter (large end up) is on the left (next to ARPS circuit board) and the tubing connector is on the right.

6.7. Verify that the ARPS tubes between the pressure pods are not kinked, dry, or too short. If this is the case, replace the tubing.

Power Supply Check

Turn on the Prismaflex control unit. Wait for the `Query` or the `Setup` screen and verify the following values:

Test Point	Signal Name	Tolerance
PIB Board		
TP14 & TP3	+5VD	5.1 to 5.3 V
TP15 & TP3	+12V	11.9 to 12.3 V
TP13 & TP3	-5V	-5.4 to -5.1 V
TP16 & TP3	+24Vm	22.8 to 25.2 V
Carrier Board		
TP2 & TP4	+5VD	5.0 to 5.3 V
Battery		
Plus & minus connector	CB (12V battery)	13.0 to 14.0 V
Plus & minus connector	CB (24V battery)	27.5 to 28.8 V

Exchange of Lead Batteries for Battery Backup

Per the battery manufacturer, the expected battery life is from 3 to 5 years for all backup batteries (both available types: +12v and +24v). Under normal use and storage premises, changing the batteries every third year will ensure operation according to specification. Battery change is guidance only; not changing every third year will not interfere with patient safety.

Service Mode - Checkout using Service Diagnose Mode

Enter Service – Diagnose mode (see Service Screens on page 6:22 for more information) and verify the proper operation and/or calibration of the components listed below:

- Pumps
- Scales
- Pressures - Pod Reposition
- Alarms Tone and Lights
- Air detector
- Syringe Pump
- Clamp and Pinch Valves
- BLD
- Internal
- Communication
- PM Timer and Date
- Clean screen
- SW configuration

If any of the items are out of calibration/specification, calibrate and/or replace as needed to correct the problem. Then, take a photograph of the bar code and send it to Gambro.

Service Screens

The service screens contains menu- and softkey-driven screens regarding calibration/diagnose procedures, on-line monitoring and testing of the main Prismaflex control unit components and systems. The service screens are divided into:

- Diagnose Screens
- Calibration Screens

Enter the service screens by pressing the time, displayed on the upper right corner of the touch screen. This can only be done at the initial start up screen.

CAUTION

! Only an authorized service technician should access the Service mode.

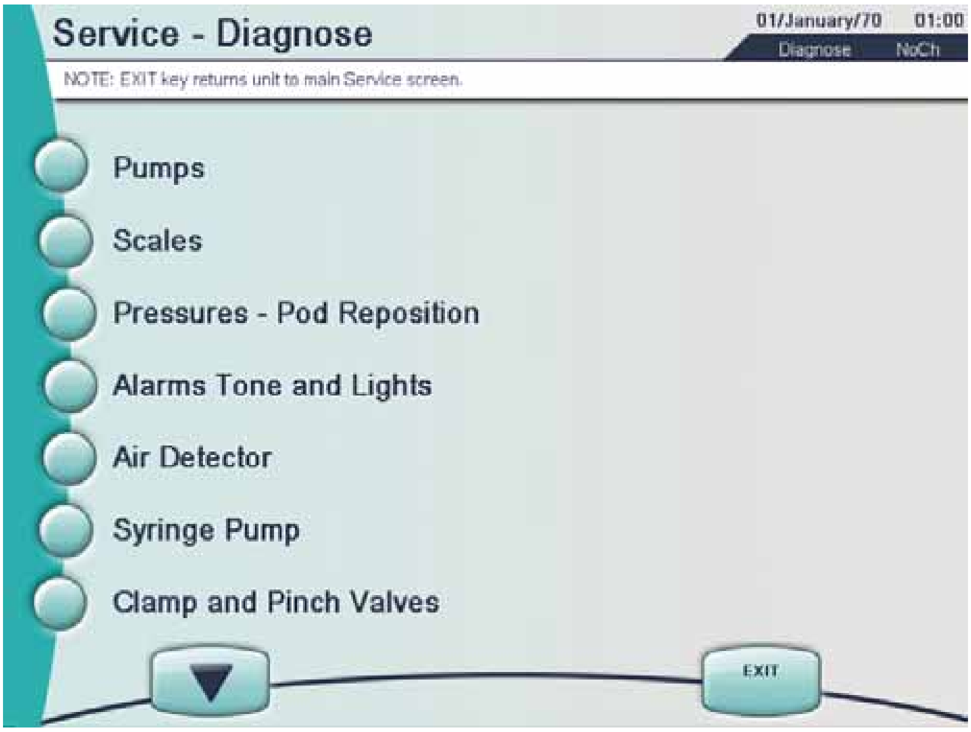
CAUTION

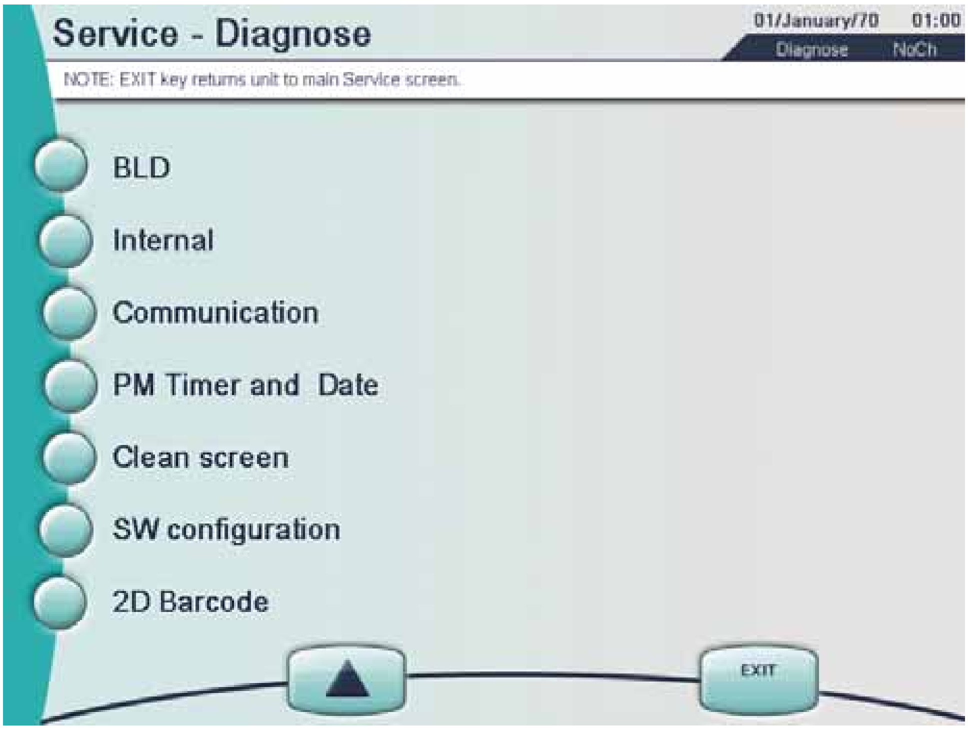
The `Service Mode` screen appears. Enter the service code and press *ENTER* softkey. The *CALIBRATE*, *DIAGNOSE*, the *RECOVER ENGLISH* and *RESTART* softkeys are highlighted and can be selected.
The *RECOVER ENGLISH* softkey is used for restoring the default English language on the Prismaflex control unit. (The Service mode is translated in the same language used for the Treatment mode). The technician must re-boot the Prismaflex control unit to allow the English language configuration file loading.
The *RESTART* softkey allows the service technican to go back to the Prismaflex start screen

Service - Diagnose Screens

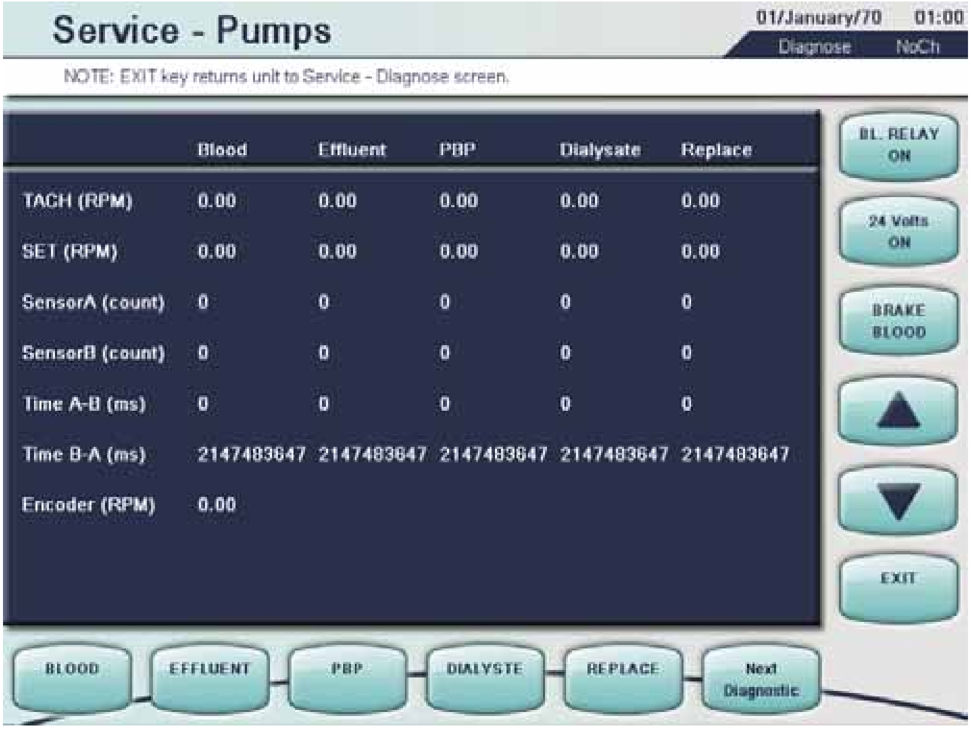
By pressing the *DIAGNOSE* softkey, screens similar to the pictures below, are displayed. Use the *UP/DOWN ARROW* softkeys to enter the different diagnose screens. Follow the instructions given on the screens to verify the proper diagnostic. If the verification fails, calibrate the component and redo the verification. If the error remains replace the component.

The *EXIT* or the *CONFIRM ALL* softkey appears on every `Service-Diagnose` screen. Each time the *EXIT* or the *CONFIRM ALL* softkey are pressed, the Prismaflex control unit returns to the initial `Service-Diagnose` screen.




Service - Diagnose
01/January/70 01:00
Diagnose NoCh
NOTE: EXIT key returns unit to main Service screen.
BLD
Internal
Communication
PM Timer and Date
Clean screen
SW configuration
2D Barcode
EXIT

Diagnose Screen – Pumps Diagnose



Data displayed on the screen are:

TACH:	value in rpm read by the Protective side
SET:	rpm set by the user with the UP/DOWN ARROW softkeys rpm range is: -90 to +90 for blood pump -250 to 250 for the other pumps Note: This is the maximum measurable range. pumps might grind if speed of 200 or more is selected and the brake is turned on/off, select a value between 180 to 200 and –180 to -200
Sensor A (count):	number of pulses accumulated for sensor A
Sensor B (count):	number of pulses accumulated for sensor B
Time A-B (ms):	delay between the time in which the magnet (on the rotor) closes the circuit of the sensor A (on the stator) and the time in which the magnet closes the circuit of the sensor B (on the stator)
Time B-A (ms):	time between B and A (as described above)
Encoder:	value in rpm read by the Protective side, based on encoder signal

Verify the functionality of the Pumps

1. Select the pump to be tested by pressing one of the *BLOOD, EFFLUENT, PBP, DIALYSATE* or *REPLACE* softkeys.

Note: Two or more motors can be tested simultaneously.

2. Press the *UP/DOWN ARROW* softkeys and release it when the desired pump speed is displayed in the `SET` row on the screen. The pump will start as soon as the *ARROW* softkey is released. The `TACH` speed should be the same as the `SET` speed (±10%).

Note: For blood pump the `TACH` and the `Encoder` value should be the same as the `SET` speed (±10%).

3. Once the pump is running, press the *DOWN ARROW* softkey to decrease the set speed again. The `TACH` speed value should still be the same as the `SET` speed (±10 %).

4. The counterclockwise direction is obtained by selecting a negative number for rpm. Once the pump is running, press the *DOWN ARROW* softkey to decrease the `SET` motor speed until a negative value is reached. Release the arrow button. Again, the `TACH` speed should be the same as the `SET` speed (±10%).

Note: Pressing the *UP ARROW* softkey increases the pump motor speed clockwise and pressing the *DOWN ARROW* softkey decreases the motor speed. (The pump motor speed is indicated in rpm, a negative value indicates counterclockwise direction).

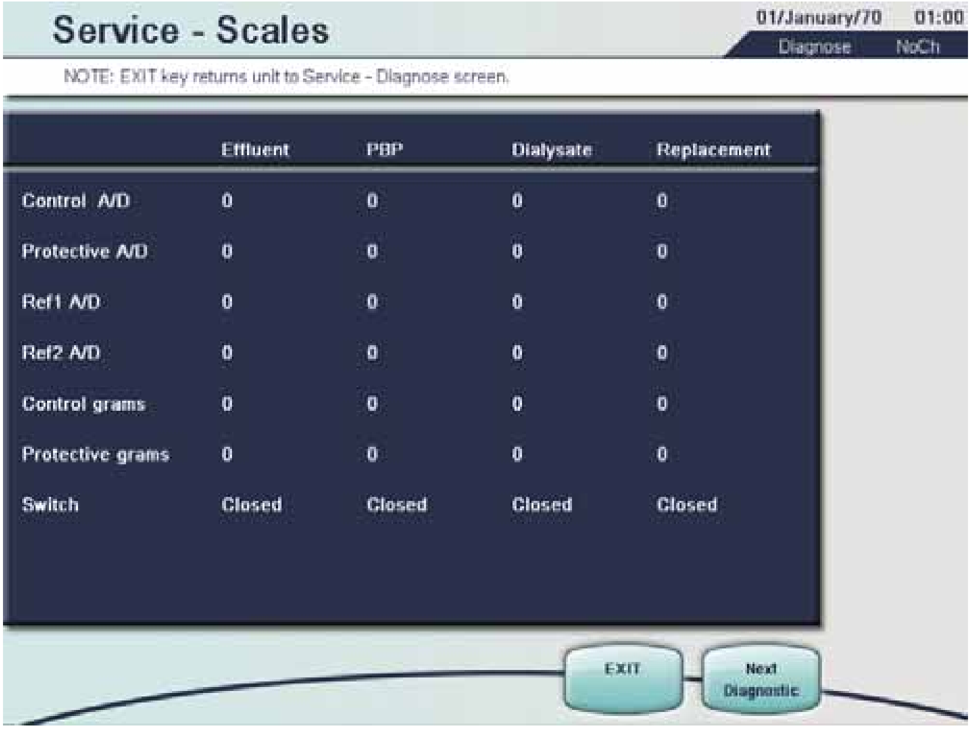
5. Disabling the 24 VDC (pressing *24 VOLTS ON* softkey) must stop the pumps. Pressing the *24 VOLTS OFF* must restart the pumps.

6. Press the *BRAKE BLOOD* softkey. The softkey changes to *UNBREAK BLOOD* and the blood pump must stop. Press the *UNBREAK BLOOD*, the blood pump must restart at the same `SET` rpm.

7. Press the *BL. RELAY ON* softkey. The softkey changes to *BL. RELAY OFF* and the blood pump must stop. Press the *BL. RELAY OFF* softkey, the blood pump must restart.

Note: Pumps shall not be started at full speed. If a pump is started at full speed, pump motor stalls and causes a loud buzzing sound. Slightly decrease the rpm value from highest setting and the pump will start normally.

Diagnose Screen – Scale Diagnose



The screen displays the averaged scale readings for the control and protective Weight Transducers, and the associated A/D values. The weight and A/D values at each Weight Transducer are continuously displayed in the row below the scale name.

Data displayed in the screen are:

`Control A/D`:	A/D value read by the channel used for the control side
`Protective A/D`:	A/D value read by the channel used for the protective side
`Ref1 A/D and Ref2 A/D`:	voltage references connected to 2 A/D channel
`Control grams`:	weight in grams read by the control side with the actual calibration parameters
`Protective grams`:	weight in grams read by the protective side with the actual calibration parameters
`Switch`:	is the indication about the status of the switch (scale open / scale close)

Verify the functionality of the Scales

1. Remove any weight on the scale.

2. Verify that the values on the screen are within the accepted values defined in “Accepted values for scale verification” below.

	Accepted values for scale verification		
	No weight on scale	5.2 kg calibration weight (part A+B) on scale	7.0 kg calibration weight (part A+B, C+D) on scale
`Control A/D`	84 000 – 93 750	103 700 – 110 450	110 000 – 116 750
`Protective A/D`	55 050 – 64 800	38 350 – 45 100	32 050 – 38 800
`Control grams`	0 ±7g	5200 ±7g	7000 ±7g
`Protective grams`	0 ±7g	5200 ±7g	7000 ±7g

3. Place the calibration weight (part A+B) on the scale and monitor the values. Verify that the values on the screen are within the accepted values defined in “Accepted values for scale verification”.

4. Place the calibration weight (part A+B, part C+D) on the scale handle and monitor the values.

5. Verify that the values on the screen are within the accepted values seen above in “Accepted values for scale verification”.

6. Gently press down the scale by hand until the Protective Grams and Control Grams on the screen shows approximately 9000g.

7. Release the scale.

8. Verify that the values on the screen are within the accepted values defined in “Accepted values for scale verification”.

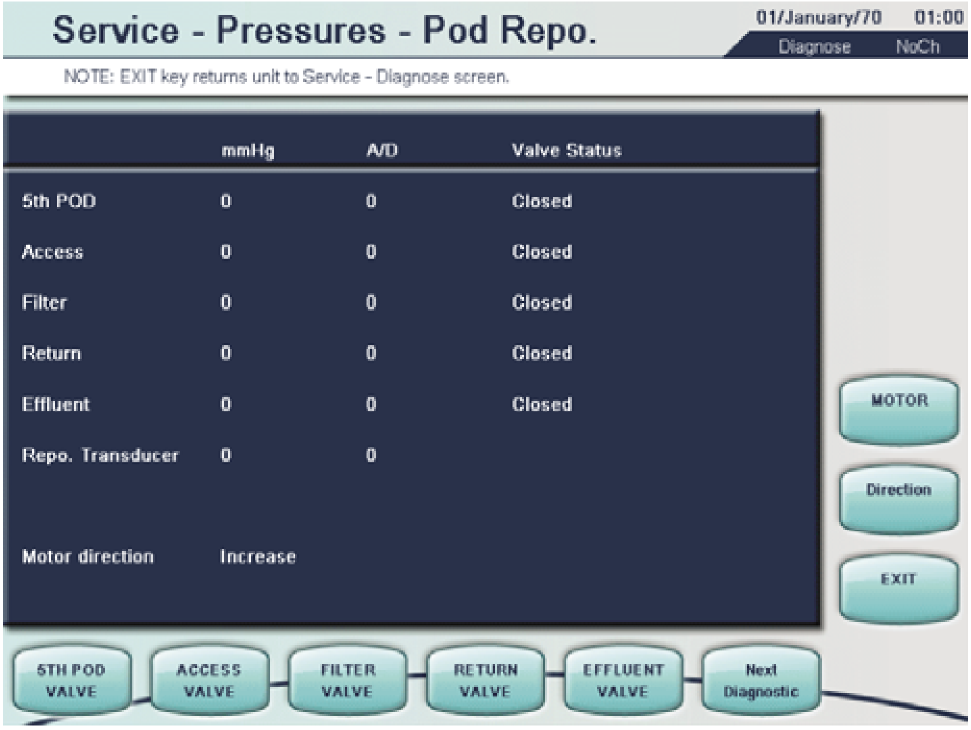
9. Gently lift the scale by hand until the Protective Grams and Control Grams on the screen shows approximately 5000g.

10. Release the scale.

11. Verify that the values on the screen are within the accepted values defined in “Accepted values for scale verification”.

12. Repeat step 3–9 for all scales.

Diagnose Screen – Pressure Pod Reposition



The screen displays the averaged pressure readings in `mmHg` and the associated `A/D` values. It also shows the status of the five valves.

Data displayed in the screen are:

`mmHg`:	pressure indication of associated valve in mmHg
`A/D`:	A/D value read by the channel
`Value Status`:	is the indication about the status of the valve (`Open / Closed`)
`Repo. Transducer`:	ARPS pump
`Motor direction`:	`Increase / Decrease`

Verify the functionality of the Pressure Pods

1. Install the pressure calibration/test tube on each of the pressure pod housings and securely onto the return pressure port.

2. Press the *ACCESS VALVE* softkey to open the access reposition valve and allow the pressure applied at the access pressure pod to register on both the reposition and access transducers.

3. With the pressure monitors open to the ambient atmospheric pressure, the pressure must read 0 ±4 `mmHg` and `A/D` should read 512 ±20.

4. To verify that all the valves are able to open, press the *ASSOCIATED* softkey. The softkey will be highlighted and the valve for the repositioning system will open. Check that each of the valves are opened one at a time.

5. Apply a pressure of -350 mmHg to all the pressure sensors. Verify that the pressure value is equal to the pressure measured by the manometer ±35 `mmHg` and verify that the `A/D` value is 162 ±35.

6. Apply a pressure of +450 mmHg to all the pressure sensors. Verify that the pressure value is equal to the pressure measured by the manometer ±45 `mmHg` and verify that the `A/D` value is 962 ±35.

Verify ARPS Repositioning

10. Press the *ACCESS VALVE* softkey. The softkey will be high lighted and the access pressure valve will open.

11. Press the *DIRECTION* softkey until the `Motor Direction` row displays `Decrease`, then press the *MOTOR* softkey to begin changing the pressure.

12. When the valve pressure displayed reaches approximately -350 mmHg, press the *MOTOR* softkey again to stop the pump. The `Reposition Press.` display should decrease at the same rate as the valve pressure display, and should be approximately the same value.

13. Repeat 10 – 12 for all the valves.

Diagnose Screen – Alarms Tone and Light

The screen displays the different lights and alarm sounds that are present in the Prismaflex control unit.

Verify the functionality of the Alarm tones and Lights

1. Press the *WARNING TONE* softkey.
   High sound, 10 sound pulses repeated approx. every 8 seconds should be heard.

2. Press the *MALFUN. TONE* softkey.
   High Sound, 10 sound pulses repeated approx. every 8 seconds should be heard.

3. Press the *CAUTION TONE* softkey.
   Medium sound, 3 sound pulses repeated approx. every 11 seconds should be heard.

4. Press the *ADVISORY TONE* softkey.
   Low sound, 2 sound pulses repeated approx. every 21 seconds should be heard.

5. Press the *CONTROL TONE* softkey.
   A light tone indicating touch screen response should be heard.

6. Press the *WARNING LIGHT* softkey.
   The red lamp will flash.

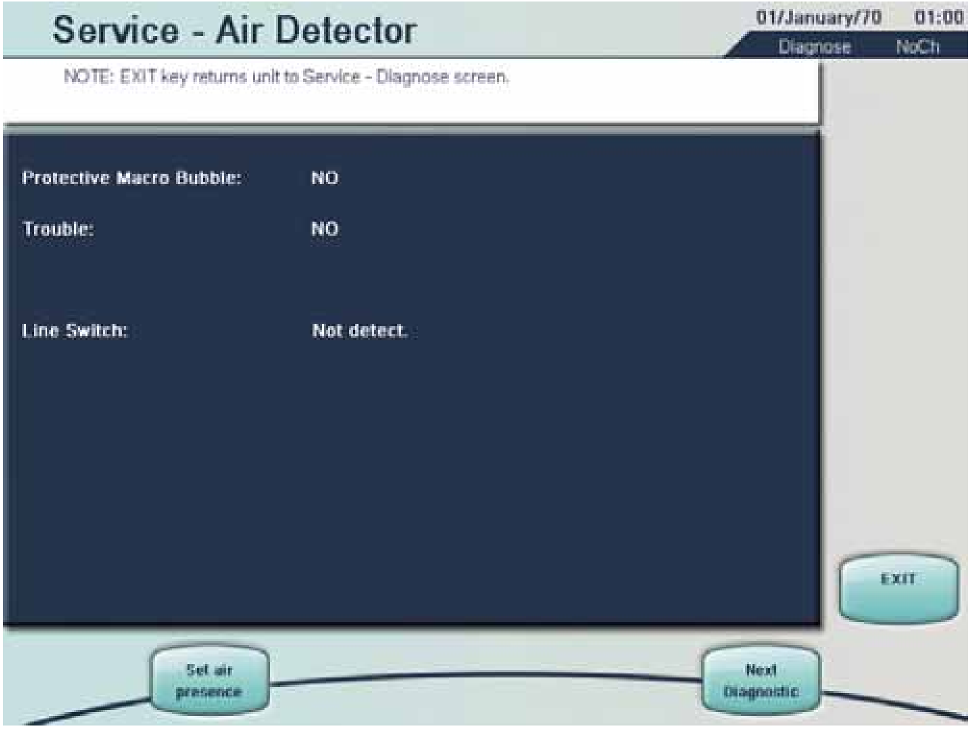
7. Press the *MALFUN. LIGHT* softkey.
   The red lamp will flash.

8. Press the *CAUTION LIGHT* softkey.
   The yellow lamp will flash.

9. Press the *ADVISORY LIGHT* softkey.
   The yellow lamp will be lit permanently.

10. Press the *GREEN LIGHT* softkey.
    The green lamp will be lit permanently.

Diagnose Screen – Air Detector



This screen is used for verifying the functionality of the ABD (Air Bubble Detector).

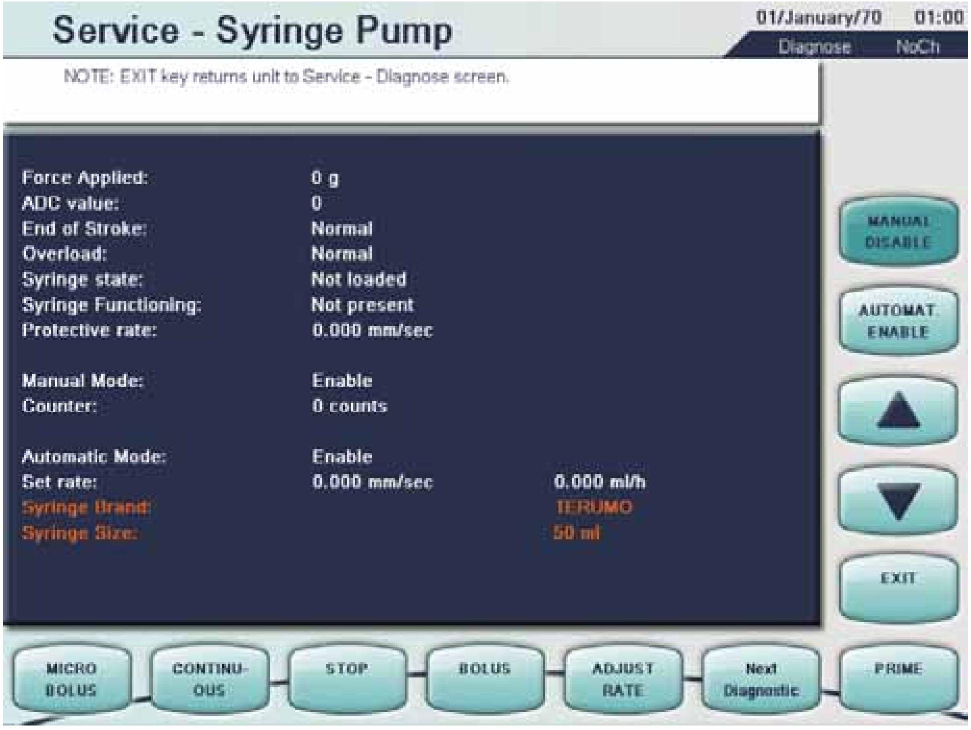
Verify the functionality of the Air Detector

1. Install a fluid-filled tube from a Prismaflex disposable set, in the Air Bubble Detector housing.
   - The Line switch should show `Line Detect`
2. Press the *SET AIR PRESENCE* softkey to simulate a macro-size air bubble.
   - The `Protective Macro Bubble` row should display `YES` or briefly display `YES`, indicating that the system has detected a macro-size bubble. The `Trouble` row should display `YES`.
   - The Line switch should show `Line Detect`.

3. Press the *SET AIR PRESENCE* softkey once again.

   - The `Protective Macro Bubble` row should display `NO`.
   - The `Trouble` row should display `NO`.

Diagnose Screen – Syringe Pump



This screen is used for verifying the different functionalities of the Syringe Pump.

Data displayed on the screen are:

`Force Applied`:	is the actual force applied to the syringe plunger clamp calculated by the actual calibration coefficients
`ADC value`:	is the AD value read by the syringe pump
`End of Stroke`:	`Normal` = no end of stroke Eos `Eos Up` = end of stroke up (not working for all types of clip holders) Eos `Eos Down` = end of stroke down
`Overload`:	this field indicates when a overload condition is reached. The overload threshold is a value syringe dependent
`Syringe state`:	indicates if the syringe is loaded or not loaded
`Syringe Functioning`:	indicates the actual condition of the syringe pump and can assume the following values: `Not present.` – if the syringe is not installed in its holder `Loading.` – if the syringe pump is loading the syringe `Wai. Hepar.` – if the syringe pump is waiting for automatic heparinisation `Adaptation` – when the heparinisation starts Normal, in working condition
`Protective rate`:	mm/s read by the Protective side. In the new software version the unit is mm/s
`Manual mode and Automatic mode`:	indicates if the mode is disabled or enabled reading the status of the syringe pump
`Counter`:	this is the number of encoder pulses measured during movement in the upwards direction, when the syringe pump is in Manual mode

`Set rate:`	is the rate set by the arrow buttons
`Syringe Brand`	Selectable in Custom mode
`Syringe Size`	Configured in Service - Calibrate - Syringe Holder Configuration

Identification of stroke length

Note: To be performed after change/installation of Syringe pump and/or software updates.

1. Use the syringe pump hard keys to move the carrier to its bottom position. Verify that the the screen shows `End of stroke: Eos Down`.

2. Use the syringe pump hard keys to move the carrier to its top position. Verify that the screen shows `End of stroke: Eos Up` and `Force Applied: 0 g`.

3. Use the syringe pump hard keys to move the carrier to its bottom position. Verify that the the screen shows `End of stroke: Eos Down`.

Weight verification (Carrier should be in central position)

1. Remove the syringe from the syringe plunger.

2. Hang the calibration weight (Part A + Part B + Part C + Part D = 7000 g) on the plunger as shown in the picture below.

3. Confirm that `Force applied` on the screen is between 6800 g and 7200 g.

4. Remove the weight from the syringe plunger.

5. Confirm that `Force applied` on the screen is between -200 g and +200 g.

Syringe State Verification

1. Enable the `Manual mode` by pressing the *MANUAL ENABLE* softkey.

2. Lower the plunger by pressing the *down* key.

3. Place a syringe with at least 15 ml of water, in the holder.

4. Connect the luer connection to a Prismaflex disposable set or an unused effluent bag in order to get some resistance in the pump movement and adjust the plunger to the 15 ml mark.

5. Press the *up* key to load the syringe properly and close the syringe latch. The message `Syringe state:  Loaded` should appear.

6. Disable the `Manual mode` by pressing the *MANUAL DISABLE* softkey.

Automatic Microbolus Verification

1. Perform Syringe State Verification above.

2. Enable the `Automatic mode` by pressing the `AUTOMAT. ENABLE` softkey.

3. Press the *ADJUST RATE* softkey. Use the *UP/DOWN ARROW* softkeys on the right side of the screen. Set the delivery rate for the syringe pump to 0,018 mm/s. The rate can be set between 0 and 0.5 mm/s.

4. Press the *MICRO BOLUS* and the *CONTINUOUS* softkey. Depending on set rate value it may take some time before the microbolus is activiated.

Continuous Delivery Verification

1. Perform Syringe State Verification above.

2. Enable the Automatic mode by pressing the *AUTOMAT. ENABLE* softkey.

3. Press the *ADJUST RATE* softkey. Use the *UP/DOWN ARROW* softkeys on the right side of the screen. Set the delivery rate for the syringe pump to 0,018 mm/s. The rate can be set between 0 and 0.5 mm/s.

4. Press the *CONTINUOUS* softkey and start the stopwatch. Verify that in 12 minutes the syringe pump delivers the quantity of anticoagulant listed in the table:

Syringe	Volume (ml)	Internal Diameter	Delivery (ml/12 min)	ml/h
Fresenius Injectomat	50	29	8.6	42.8
Terumo	50	29	8.6	42.8
B. Braun (Perfusor)	50	28	6.7	39.9
B. Braun (Omnifix)	50	27.9	7.9	39.6
Codan Luer Lock	50	27.7	7.8	39.1
Kendall Monoject	50	26.6	7.2	36.0
BD Plastipak	50	26.4	7.1	35.5
Terumo	30	23.3	5.5	27.6
B. Braun (Omnifix)	30	22	4.9	24.6
BD Plastipak	30	21.7	4.8	24.0
B. Braun (Omnifix)	20	20.2	4.2	20.8
Kendall Monoject	20	20.1	4.1	20.6
Terumo	20	20	4.1	20.4
BD Plastipak	20	19	3.7	18.4

5. When the syringe pump is operating, the displayed value for the `Protective rate` changes, indicating that the monitor microprocessor is receiving the stepper motor signal increments. The `Protective rate` and the `Set rate` should be the same.

6. When the delivery rate accuracy is verified, press the *STOP* softkey.

Automatic Bolus Verification

1. Perform Syringe State Verification above.

2. Enable the Automatic mode and press the *BOLUS* softkey and start the stopwatch at the same time.

3. The syringe pump should deliver a 5 ±0.5 ml bolus in a time reported in the table:

Syringe	**Volume (ml)**	**Internal Diameter**	**Delivery time (sec.)**
Fresenius Injectomat	50	29	15
Terumo	50	29	15
B. Braun (Perfusor)	50	28	16
B. Braun (Omnifix)	50	27.9	16
Codan Luer Lock	50	27.7	17
Kendall Monoject	50	26.6	18
BD Plastipak	50	26.4	18
Terumo	30	23.3	23
B. Braun (Omnifix)	30	22	26
BD Plastipak	30	19	27
B. Braun (Omnifix)	20	20.2	31
Kendall Monoject	20	20.1	32
Terumo	20	20	32
BD Plastipak	20	19	35

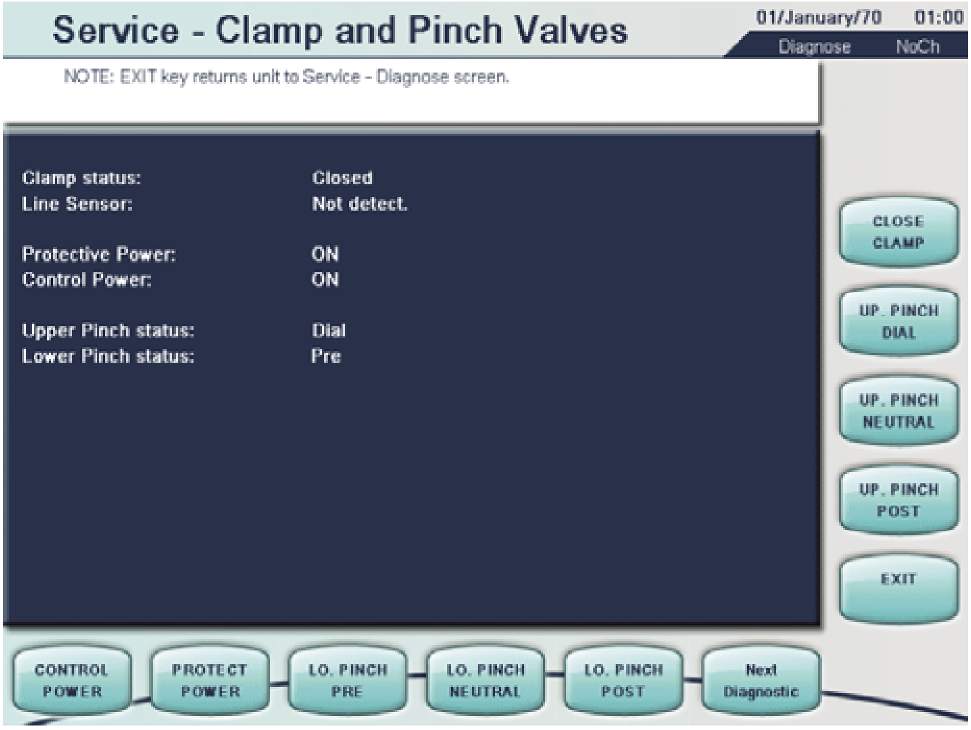
Prime verification

1. Perform Syringe State Verification above.

2. Enable the Automatic mode and press the *PRIME* softkey.

3. Verify that approx. 1 ml has been delivered.

Diagnose Screen – Clamp and Pinch Valves



This screen is for verifying the functionality of the Clamp and the Pinch Vales.

Verify the functionality of the Clamp

1. Press the *CLOSE CLAMP* softkey to close and open the line clamp.

2. Make sure the clamp is open. Press the *CONTROL POWER* softkey. The clamp should close and the `Clamp status` display should also indicate a closed reading. The display related to the *CONTROL POWER* softkey should indicate `OFF`.

3. To open the clamp, press the *CONTROL POWER* softkey until the display reads `ON`.

4. Press the *PROTECT POWER* softkey. The clamp should close and the `Clamp status` display should also indicate a closed reading. The display related to the *PROTECT POWER* softkey should indicate `OFF`.

5. To open the clamp, press the *PROTECT POWER* softkey until the display related to the softkey reads `ON`.

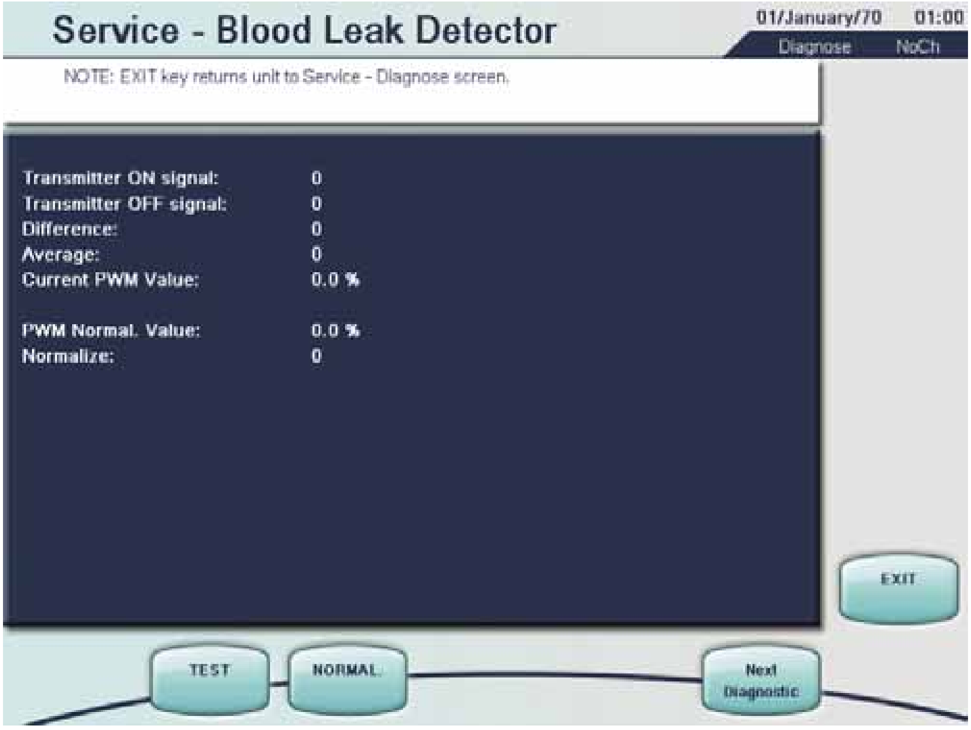
Verify the functionality of the Lower Pinch Valve

6. Lower Pinch valve: Install a tubing segment from a Prismaflex disposable set in the lower pinch valve. Press each position softkey (*LO. PINCH PRE*, *LO. PINCH NEUTRAL*, and *LO. PINCH POST*) and verify that the pinch valve changes to the correct position.

Verify the functionality of the Upper Pinch Valve

7. Upper Pinch valve: Install a tubing segment from a Prismaflex disposable set in the upper pinch valve. Press each position softkey (*UP. PINCH DIAL*, *UP. PINCH NEUTRAL*, and *UP. PINCH POST*) and verify that the pinch valve changes to the correct position.

Diagnose Screen – BLD (Blood Leak Detector)



This screen is for verifying the functionality of the BLD.

Note: The `Normalize` value that appears after the *NORMAL.* softkey is pressed is stored only for use during the current Service mode. The Blood Leak Detector `Normalize` value is re-calibrated and stored during the Prime Self-Test.

Tools needed: Effluent tubing segment from a Prismaflex disposable set

Verify the functionality of the Blood Leak Detector

1. Remove the tubing segment from the holder and press the *NORMAL.* softkey.

2. Verify that the `PWM Normal Value` is <15%.

3. Install an empty tube in the BLD holder and press the *NORMAL.* softkey (wait until the `PWM Normal Value` is updated).

4. Press the *TEST* softkey, this will generate a `Malfunction: Prime Self Test` (code 18).

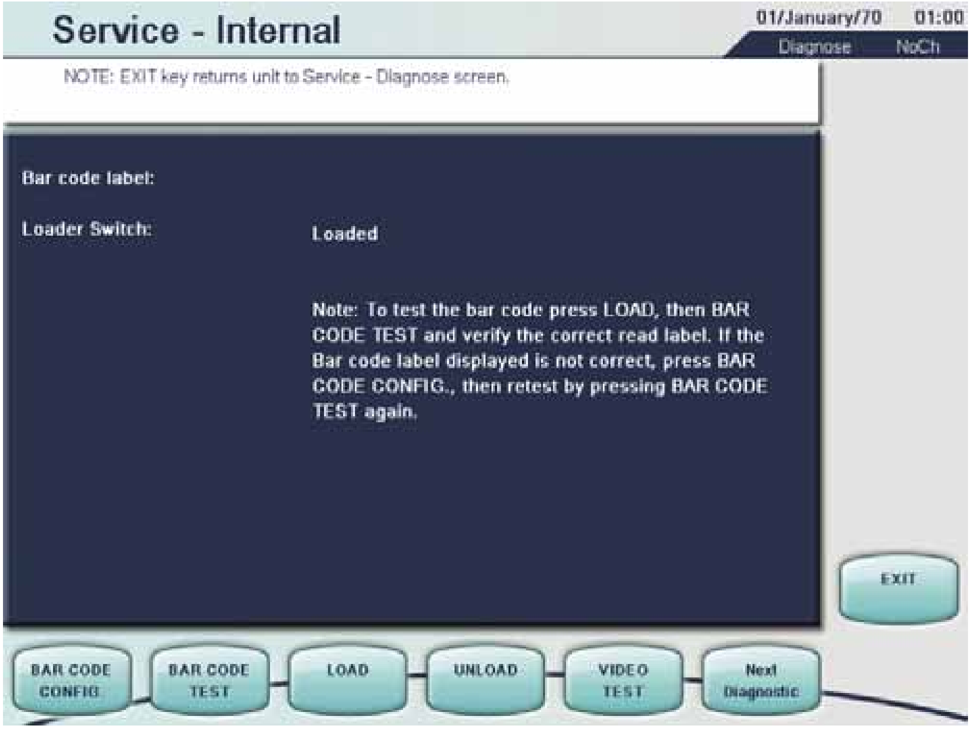
5. Verify that the `PWM` transmitter is >30%. Press the *NORMAL.* softkey.

6. Fill the tubing segment with water and install it in the blood leak detector housing.

7. Press the *NORMAL.* softkey.

8. Wait for BLD normalization. Verify that the transmitter `PWM` is in the range <45% and that the normalization value is 43500 ±1500.

Diagnose Screen – Internal



This screen is for verifying the functionality of the Bar code reader and Loader.

Verify the functionality of the Loader

Note: Both when the *LOAD* and *UNLOAD* softkey is pressed, all the pumps run clockwise (CW). If the loader is in the inner position press the *UNLOAD* softkey to get it back to the outer position.

1. Press the *LOAD* softkey. The cartridge loader clamp should be in the "out" position. Pressing the softkey should cause the cartridge loader to retract, and the pumps should turn in the proper direction.

2. Press the *UNLOAD* softkey and verify that the pumps turn clockwise and that the cartridge clamp loader moves in the appropriate direction.

Verify the functionality of the Bar Code Reader

3. Load a Prismaflex disposable set. Pressing the *BAR CODE TEST* softkey the label read must appear in the `Bar code label` row.

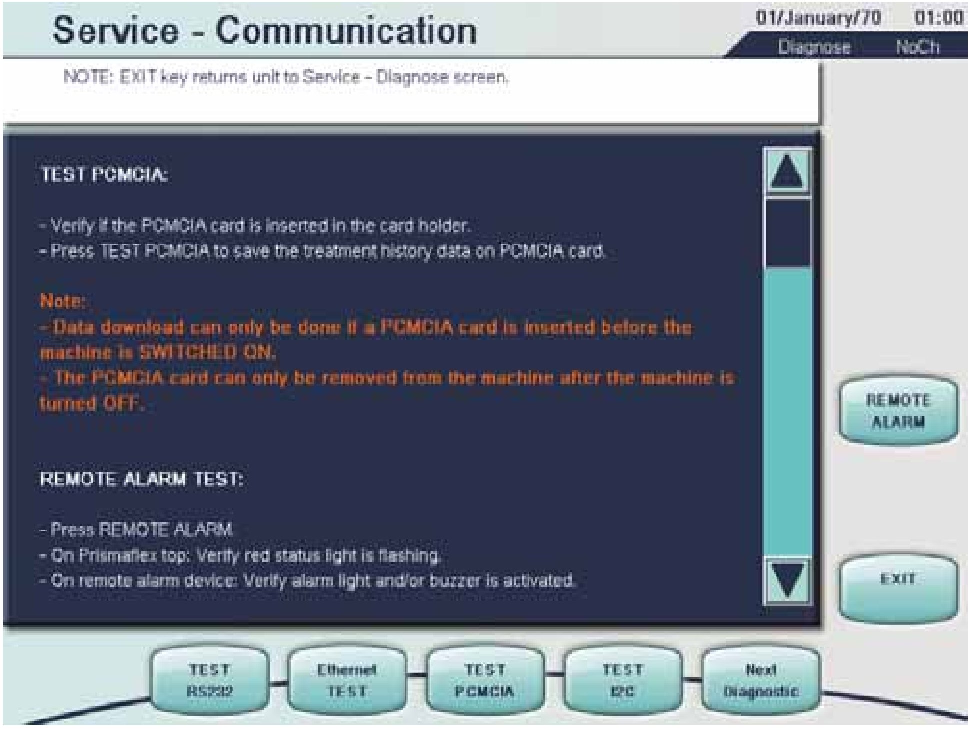
4. If the bar code reader is not able to read the label the following text appears `Bar code label: Er`. Press the *BAR CODE CONFIG* softkey: a different bar code reader configuration is set. Retry to press the *BAR CODE TEST* softkey.

5. Press the *UNLOAD* softkey and verify that the pumps turn clockwise and the set is unloading.

6. Remove the set.

Note: The *VIDEO TEST* softkey is not yet implemented.

Diagnose Screen – Communication

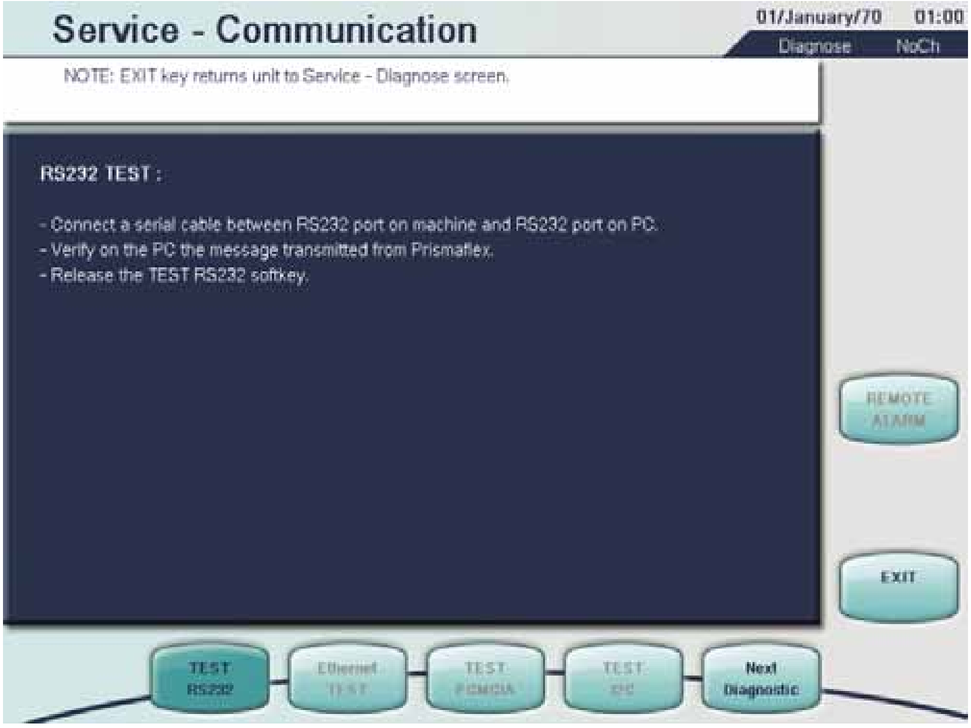


This screen is for verifying the external communication. This section should only be performed if an external communication is connected.

Note: A PC and software for reading data coming from RS232, Ethernet, are necessary to perform the following tests.

After each test is verified, release the corresponding softkey.

TEST RS 232 (When applicable)



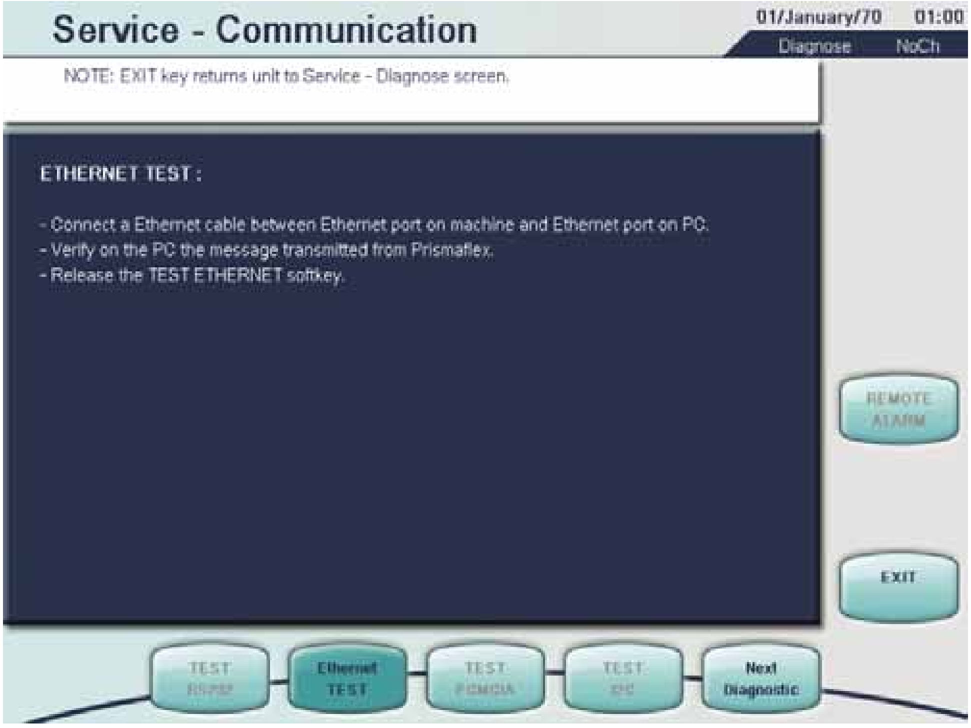
Verify the Test RS 232

1. Press the *TEST RS232* softkey. The above screen is displayed.

2. Verify on the PC that the message transmitted from the Prismaflex control unit is according to the following table;

RS 232 TEST	Field	Description
1	STX	Constant value
2	CRC	CRC of the message sent
3	Prismaflex control unit Identifier	Numerical value used to identify the Prismaflex control unit by the clinical software
4	Clinical SW identifier	Not implemented
5	Message counter	Not used in a service message; this is used to combine question and its answer
6	Command code	Not implemented
7	Message information	Number of record in message body
8	Flags	Field for Boolean values
9	Patient ID	No patient is selected in Service mode
10	SW revision	Prismaflex SW revision
11	Therapy type	In Service mode no therapy is selected so the value is `NOT CHOSEN`
12	Therapy status	Not therapy is selected, but user is in Service mode `STATO CALIBRATION`
13	Time	Current time
14	Message body length	Number of records sent

TEST Ethernet (When applicable)



Verify the Test Ethernet

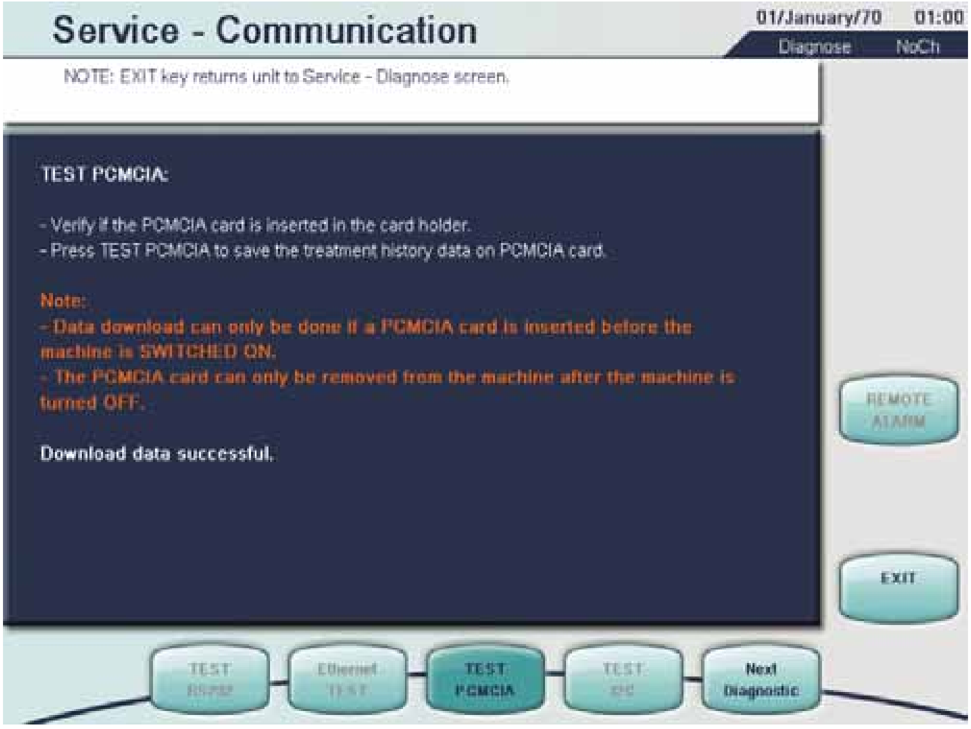
1. Press the *TEST ETHERNET* softkey; the screen above is displayed.

2. Connect an Ethernet cable between the Ethernet port on the Prismaflex control unit and the Ethernet port on PC.

3. Verify on PC the message transmitted from Prismaflex control unit.

Ethernet Test	Field	Description
1	STX	Constant value
2	CRC	CRC of the message sent
3	Prismaflex control unit Identifier	Numerical value used to identify the Prismaflex control unit by the clinical software
4	Clinical SW identifier	Not implemented
5	Message counter	Not used in a service message; this is used to combine question and its answer
6	Command code	Not implemented
7	Message information	Number of record in message body
8	Flags	Field for Boolean values
9	Patient ID	No patient is selected in Service mode
10	SW revision	Prismaflex SW revision
11	Therapy type	In Service mode no therapy is selected so the value is NOT CHOOSEN
12	Therapy status	Not therapy is selected, but user is in Service mode STATO CALIBRATION
13	Time	Current time
14	Message body length	Number of records sent

TEST PCMCIA



Verify the TEST PCMCIA

1. Make sure that a technical data card is inserted in the card reader before the Prismaflex control unit boots-up. If the technical data card is not inserted, switch off the Prismaflex control unit, insert a technical data card and switch on the Prismaflex control unit again. Enter the `Service - Communication` screen.

2. Press the *TEST PCMCIA* softkey, the screen above is displayed.

3. Wait for data download.

4. Switch off the Prismaflex control unit and remove the technical data card from its reader.

5. Read data stored on the technical data card and verify that a *.LOX file is located in folder for current year. The *.LOX file shall have a time stamp that corresponds to the time displayed on screen.

File name is interpreted in the following way (1XZC6J7I.LOX used as an example):

File name is based on following structure:

SSSYMDHM.* (time is based on download time)

- SSS Device serial (Base36, zero padded)
- Y Year since 2000 (Base36)
- M Month (Base36)
- D Day (Base36)

- H Hour of day (Base36)
- M Last even minute of hour (Base36)

The file used as an example gives following values:

1XZ = 2519 (serial number of the Prismaflex control unit)

C = 12 (Year 2012)

6 = June

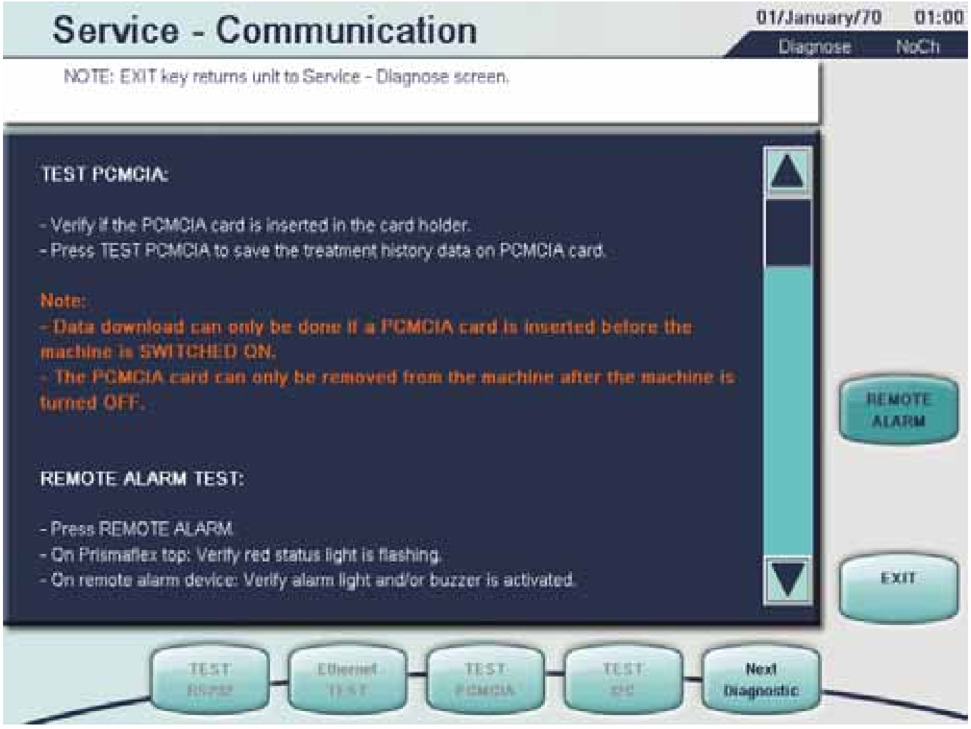
J = 19

7 = 7 (7 AM)

I = 18

Copied file comes from a Prismaflex control unit with serial number 2519 and time for the download was 7:18, 19th of June, 2012.

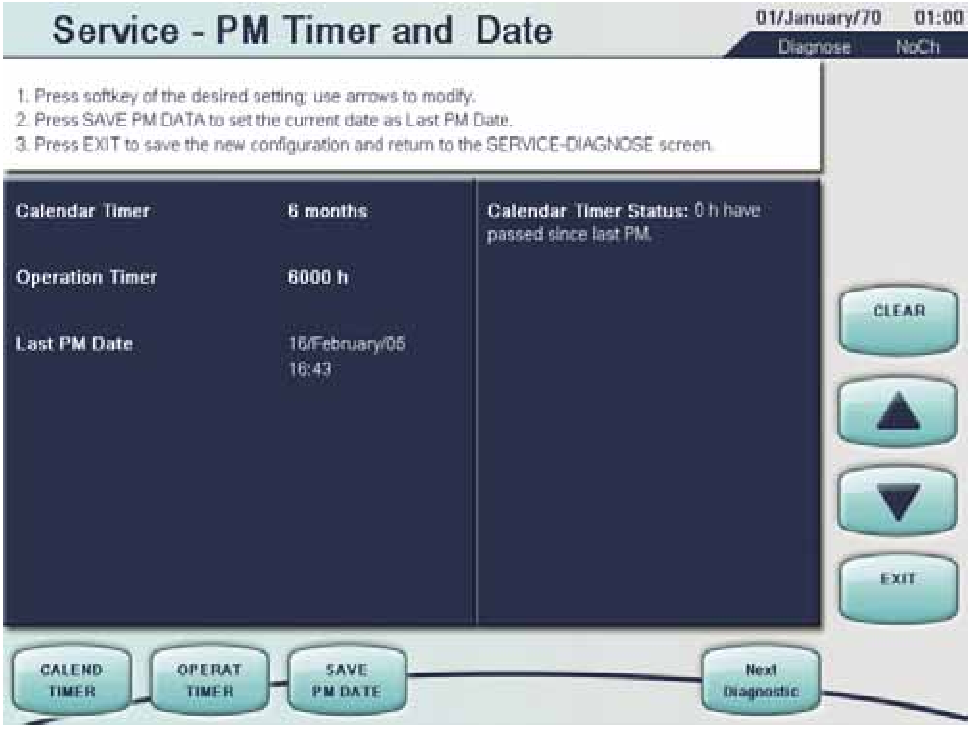
TEST REMOTE CONTROL



Verify the TEST REMOTE CONTROL (When applicable)

1. Press the *REMOTE CONTROL* softkey.
2. Verify that the red status light is on.
3. On the remote alarm device, verify that alarm light and/or buzzer is activated.

Diagnose Screen – PM timer and Date



This screen is used for setting the Last PM Date and the time interval for PM advisory. See section “Preventive Maintenance” on page 6:13.

Data displayed in the screen are:

Calendar Timer:	shows the interval time for the next occurrence of the Advisory "Preventive Maintenance Due" and is setable in the range between 1 month and 5 years with steps of 1 month
Operation Timer:	This interval is setable in the range between 500 hour and 6000 hour
Last PM Date:	shows the date of the last service intervention

Verify the PM Timer and Date

1. Press the *CALENDAR TIMER* softkey to see the current setting for the Advisory “Preventive Maintenance Due”. Use the *UP/DOWN ARROW* softkeys to modify the setting.

2. Press the *OPERAT TIMER* softkey to set the next occurrence of the Advisory “Preventive Maintenance Due”. Use the *UP/DOWN ARROW* softkeys to modify the setting.

3. Press the *SAVE PM DATE* softkey to save the current date. The date is stored as the `Last PM Date`.

Diagnose Screen – Clean Screen

This screen disables the softkeys on the screen for 10 seconds in order to clean the screen.

1. Press the *DISABLE KEYS* softkey to display a white screen without any softkey.

2. The white screen without any softkeys will be displayed for approximately 10 seconds.

Diagnose Screen – SW Configuration

Verify the SW Configuration

This screen displays, for each of the listed items, the revision level and the CRC value path, of the application and of the booter.

Diagnose Screen – 2D Barcode

Bar code

The bar code contains information about the setup and configuration of the machine, such as hardware/software configuration and calibration parameters.

The bar code gives valuable information for troubleshooting and complaint handling.

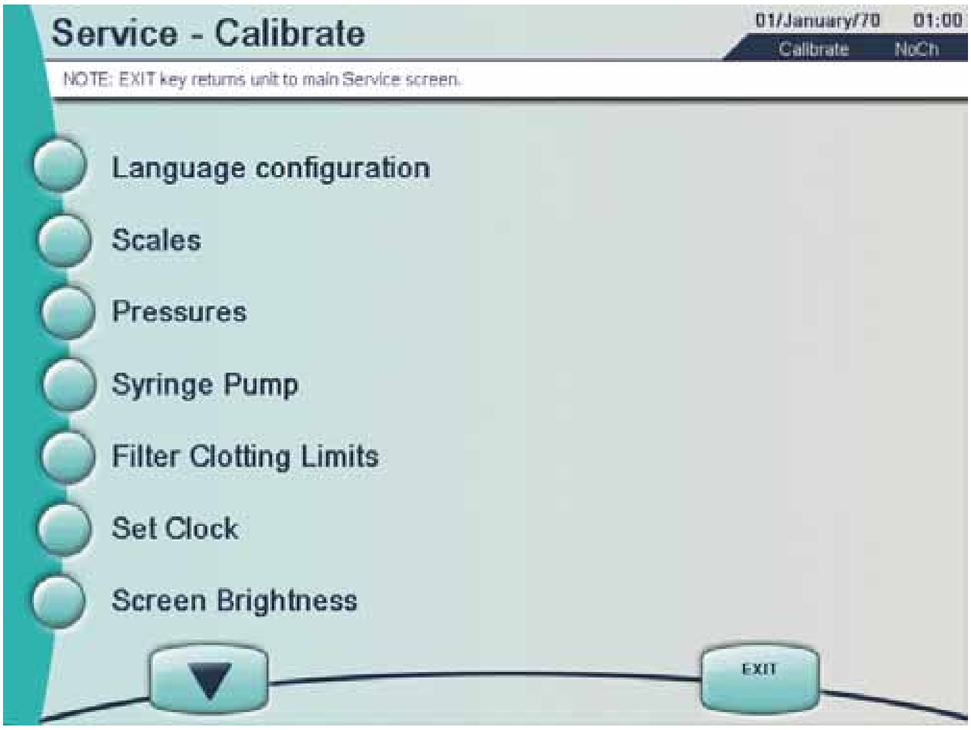
Photograph the bar code

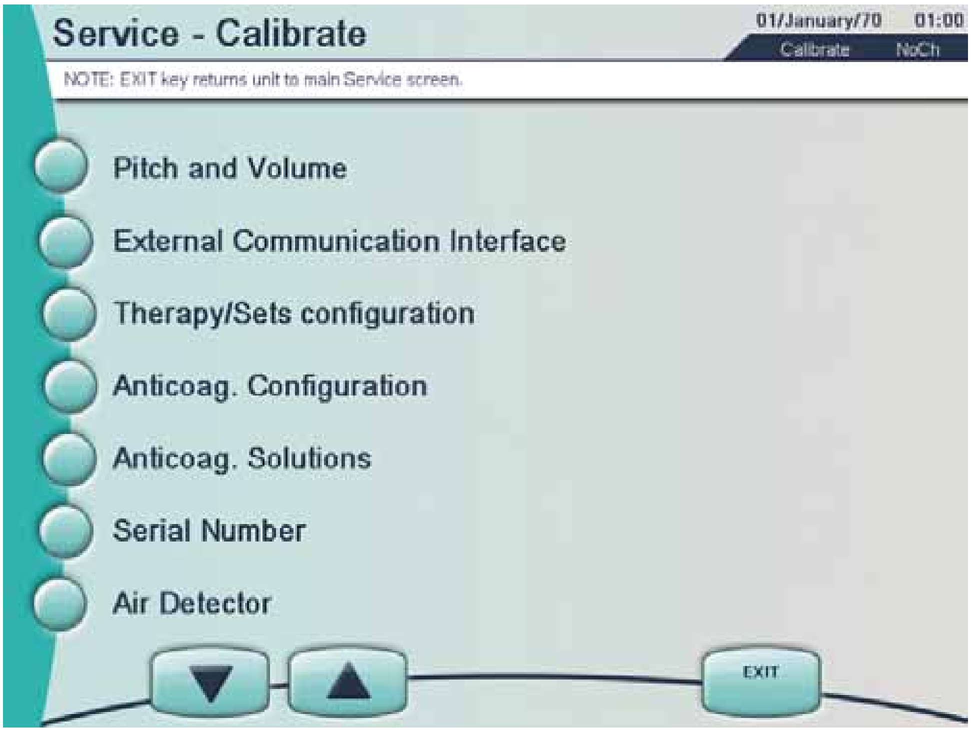
Use a digital camera to be able to take a photograph of the bar code and send it to Gambro. Take the photograph straight from the front. It is important there are no reflections caused by the flash or other light near the display.

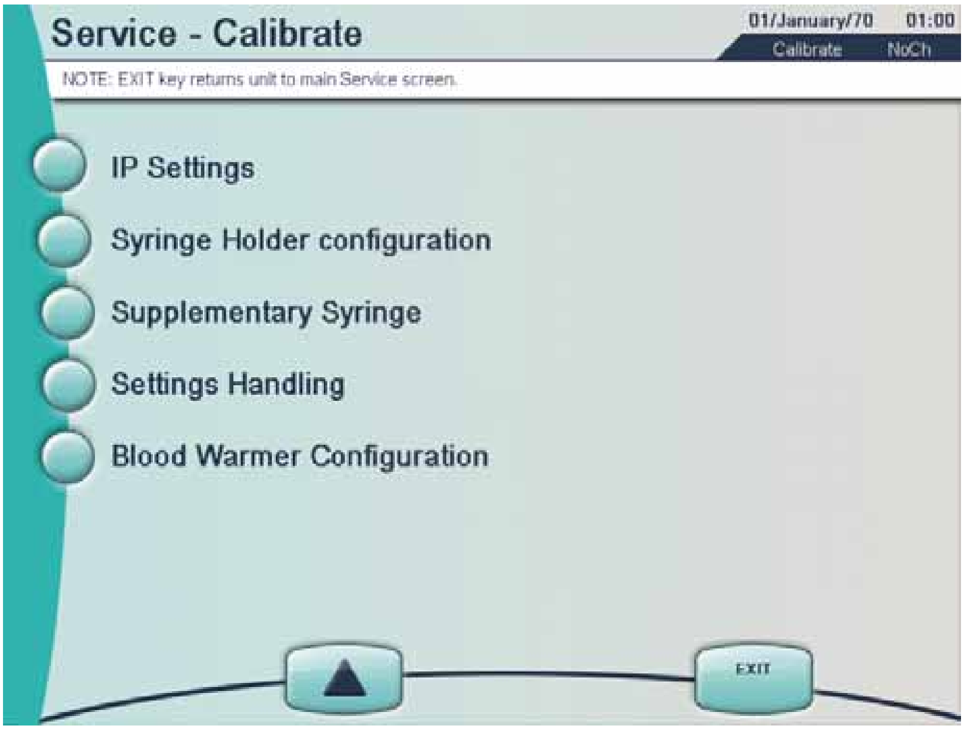
Service Calibration Screens

By pressing the *CALIBRATE* softkey, screens similar to the pictures below, are displayed. Use the *UP/DOWN ARROW* softkeys to enter the different calibration screens. Follow the instructions given on the screens to verify the proper calibration.
If the calibration fails, repair or replace the affected component/item.
If any items are out of calibration, calibrate and/or replace as needed to correct the problem.

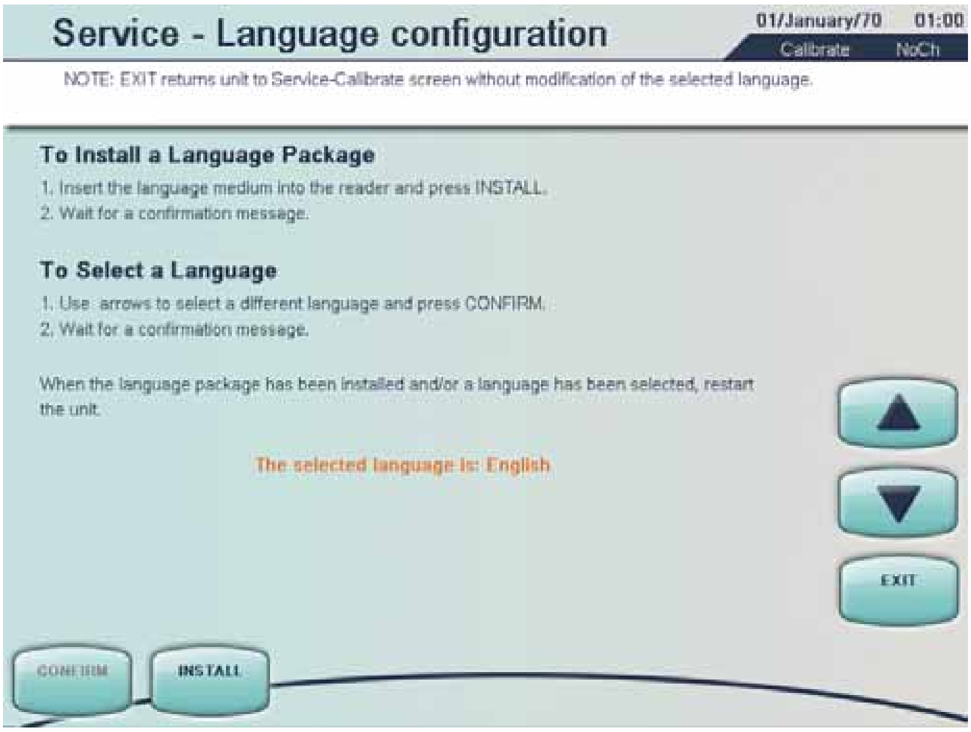
The *EXIT* or the *CONFIRM ALL* softkey appears on every `Service-Calibrate` screen. Each time the *EXIT* or the *CONFIRM ALL* softkey are pressed, the Prismaflex control unit returns to the initial `Service-Calibrate` screen.




Service - Calibrate
01/January/70 01:00
Calibrate NoCh
NOTE: EXIT key returns unit to main Service screen.
Pitch and Volume
External Communication Interface
Therapy/Sets configuration
Anticoag. Configuration
Anticoag. Solutions
Serial Number
Air Detector
EXIT


Service - Calibrate
01/January/70 01:00
Calibrate NoCh
NOTE: EXIT key returns unit to main Service screen.
IP Settings
Syringe Holder configuration
Supplementary Syringe
Settings Handling
Blood Warmer Configuration
EXIT

Calibration Screen – Language Configuration



Install a Language Package

1. Open the back of the Prismaflex control unit (use the 8 mm Hex) and insert the Prismaflex Language Medium into the reader.

2. Press *INSTALL* softkey to start copying language package from medium to Prismaflex control unit.

3. Remove medium. Restart the Prismaflex control unit.

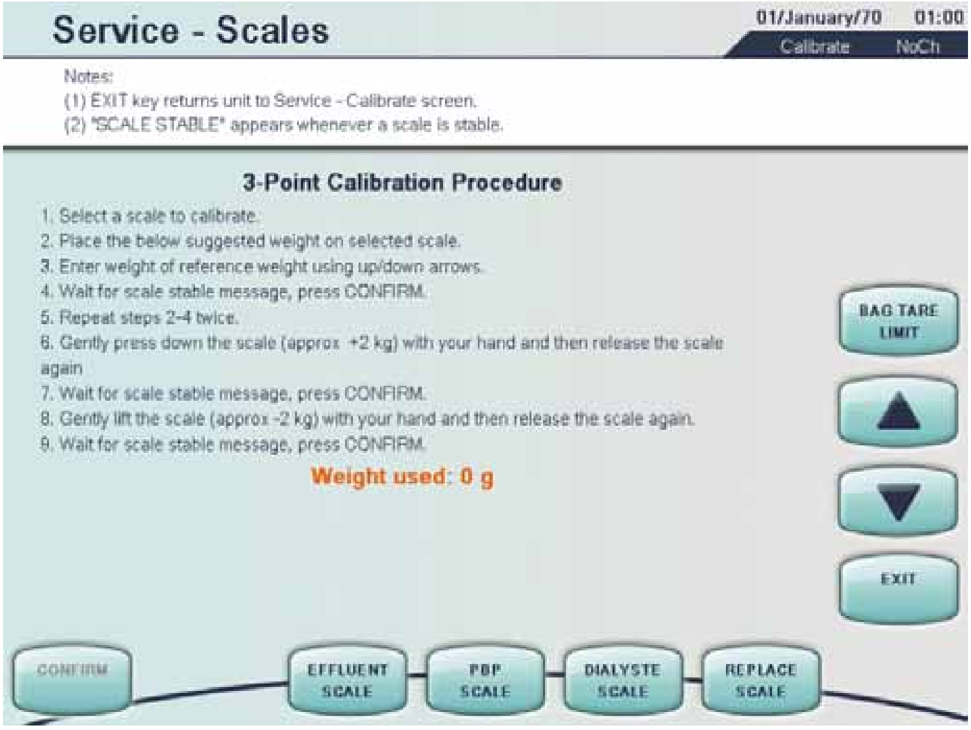
Configure the Language

1. Use the *UP/DOWN ARROW* softkeys to select requested language and press the *CONFIRM* softkey to confirm the selection.

2. Wait until a confirmation message is displayed.

3. Restart the Prismaflex control unit.

Calibration Screen – Scales Calibration



3-Point Calibration Procedure

A 3-point calibration procedure is used to calibrate the scales. The recommended weights are:

- first point 0 g
- second point 5200 g
- third point 7000 g

Tools needed: a reference weight

WARNING

⚠ The used calibration weight must correspond to the weight set in the `Service - Scales` screen (Part A + Part B = 5200 g and Part C + Part D = 1800 g).
Failure to use the corresponding weight at the second and third calibration point can cause serious injury or death to the patient.

WARNING

Calibrate the Scale

1. Select the scale to be calibrated by pressing the softkey.
2. Make sure the scale is closed during the calibration.
3. Wait for the scale to stabilized for the first calibration point, 0 g. Press *CONFIRM* when the message `Scale STABLE` appears.
4. Place the recommended weight on the selected scales middle hook. (If another reference point than 5200 g is chosen, place the weight on the selected scale and enter the weight of reference using the *UP/DOWN ARROW* softkeys.)

5. Press *CONFIRM* when the message `Scale STABLE` appears.

6. Let the 5200 g weight hang on middle hook and place the 1800 g weight on one of the selected scales outer hooks. (If another reference point than 7000 g is chosen, place the weight on the selected scale and enter the weight of reference using the *UP/DOWN ARROW* softkeys.)

7. Press *CONFIRM* when the message `Scale STABLE` appears.

Note: If the values read from the scale at the first calibration point are outside the valid intervals, the message `Scale out of tolerance, cannot be calibrated` appears on the screen. In this case the scale is damaged, and needs to be replaced.
If the values read from the scale at the second or third calibration point are outside the valid intervals, check that the correct weight is used. Then make sure that the correct weight value is entered and press the *RETRY* softkey.

Verify the Scale

8. Gently press down the scale (approx. + 2 kg) by hand and then release the scale again.

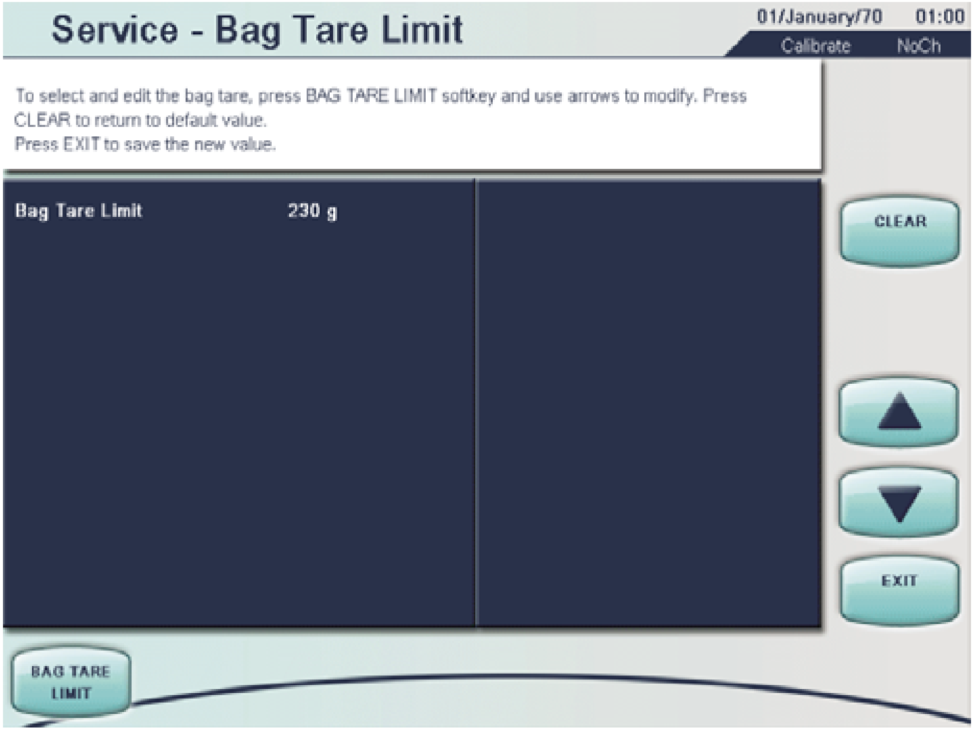
9. Wait for the `Scale STABLE` message, press *CONFIRM* softkey.

10. Gently lift up the scale (approx. – 2 kg) by hand and then release the scale again.

11. Wait for the `Scale STABLE` message, press *CONFIRM* softkey.

12. Repeat for all the scales.

When a correct calibration has been performed, the message `CALIBRATION COMPLETE` appears on the screen.



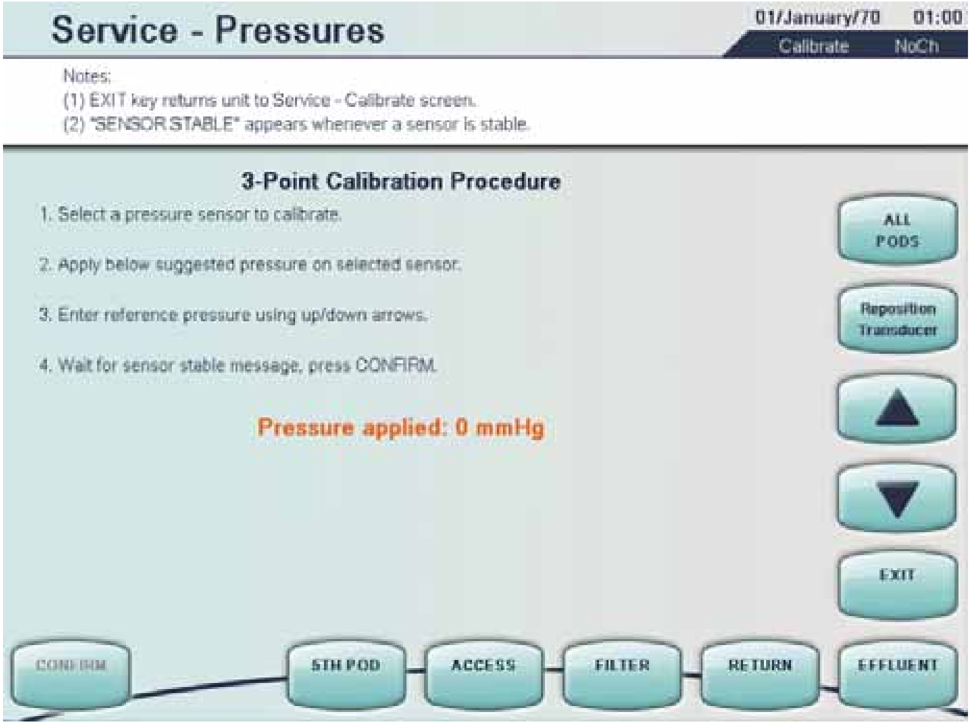
Adjust Bag Tare Limit

1. Press *BAG TARE LIMIT* softkey.

2. In `Service - Bag Tare Limit` screen, press *BAG TARE LIMIT* softkey and use *UP/DOWN ARROW* softkeys to modify tare weight for Fixed Empty Bag method.

3. Press *EXIT* softkey to save the new value and return to `Service - Scales` screen.

Calibration Screen – Pressure Sensors Calibration



3-Point Calibration Procedure

The 3-point calibration procedure is used to calibrate all the six pressure transducers; Access, Effluent, Filter, Return, 5th Pod and Reposition transducer.
Recommended pressure values are:

- first point = 0 mmHg
- second point = +400 mmHg
- third point = -400 mmHg

Tools needed: pressure calibration tube, a pressure reference instrument, 3 - way stop cock with luer connections and a syringe to apply pressure.

WARNING

⚠ If calibration fails repeatedly, replace the pressure sensor.

WARNING

Calibrate the Pressure Sensors

1. Select all the pressure sensors by pressing the *ALL PODS* softkey.
2. Wait for the sensor to stabilize for the first recommended pressure, 0 mmHg. Press *CONFIRM* when the message `Sensor STABLE` appears.
3. Attach the pressure calibration tube.
4. Apply the second recommended pressure (+400 mmHg).

5. Wait for `Sensor STABLE` message. Press *CONFIRM*.

6. Enter reference value using the *UP/DOWN ARROW* softkeys (range - 500 to 500 mmHg). Press *CONFIRM*.

7. Apply the third recommended pressure (-400 mmHg). Press *CONFIRM*.

8. Wait for `Sensor STABLE` message. Press *CONFIRM*.

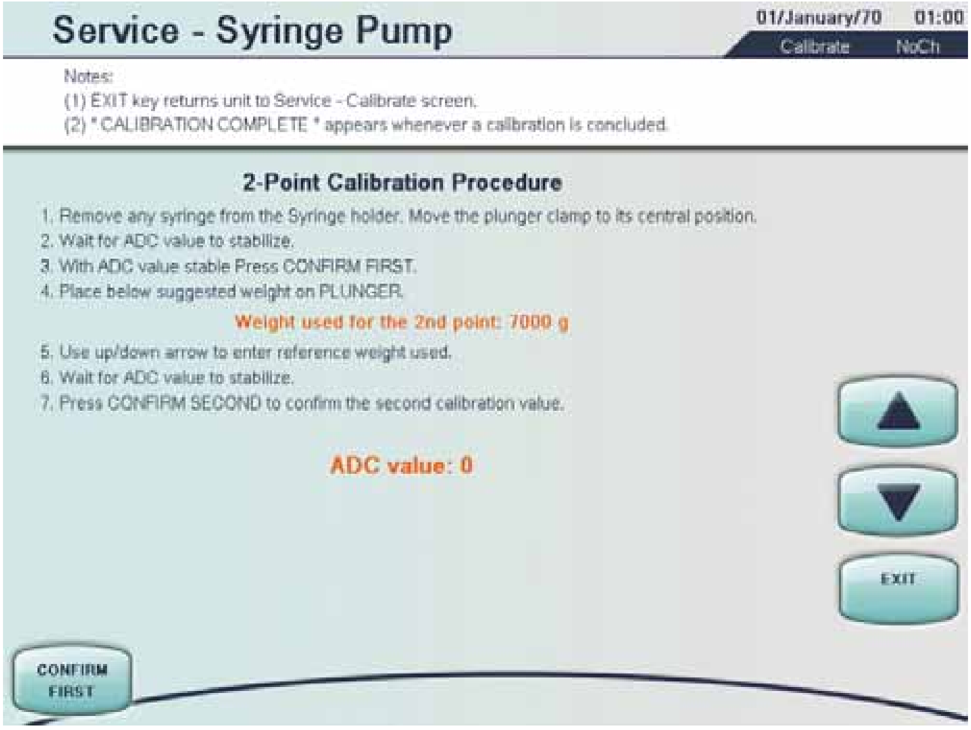
9. Enter reference value using the *UP/DOWN ARROW* softkeys (range - 500 to 500 mmHg). Press *CONFIRM*.

10. `CALIBRATION COMPLETE` appears on the screen.

11. If the test fails, repeat the above for all the pressure sensors one at a time.

Note: To calibrate the reposition transducer, the pressure must be inserted from the access pod. The access reposition valve opens when the *REP TRAN* softkey is pressed.

Calibration Screen – Syringe Pump Calibration



2-Point Calibration Procedure

Tools needed: a reference calibration weight between 7000 and 9999 g. The weight must be put on the syringe plunger clamp and must not touch the Prismaflex control unit.

WARNING

⚠ The used calibration weight must correspond to the weight set in the `Service - Syringe Pump` screen (Part A + Part B + Part C + Part D = 7000 g).
Failure to use the corresponding weight at the second calibration point can cause serious injury or death to the patient.

WARNING

Calibrate the Syringe Pump

1. Remove any syringe from the Syringe holder.
2. Move the plunger clamp to the same level as the tubing guide for the Effluent and PBP line, use the *up/down arrow* hard keys, located above the syringe pump.
3. Wait for the ADC value to stabilize.
4. With the ADC value stable, press the *CONFIRM FIRST* softkey.
5. Hang the calibration weight (Part A + Part B + Part C + Part D = 7000 g) on the plunger according to the picture.

6. Use the *UP/DOWN ARROW* softkeys to enter the reference weight.

7. Wait for the `ADC value` to stabilize.

8. Press the *CONFIRM SECOND* softkey to confirm the second calibration value.

9. `CALIBRATION COMPLETE` appears on the screen.

10. Note: After change/installation of the Syringe pump and/or software updates, “Identification of stroke length” must be performed. See section ”Diagnose Screen – Syringe Pump” starting on page 6:36.

Reset offset

1. Remove any weight from the Syringe plunger.

2. If the `Weight Applied` is different from zero, press *ZEROING* to reset the syringe offset.

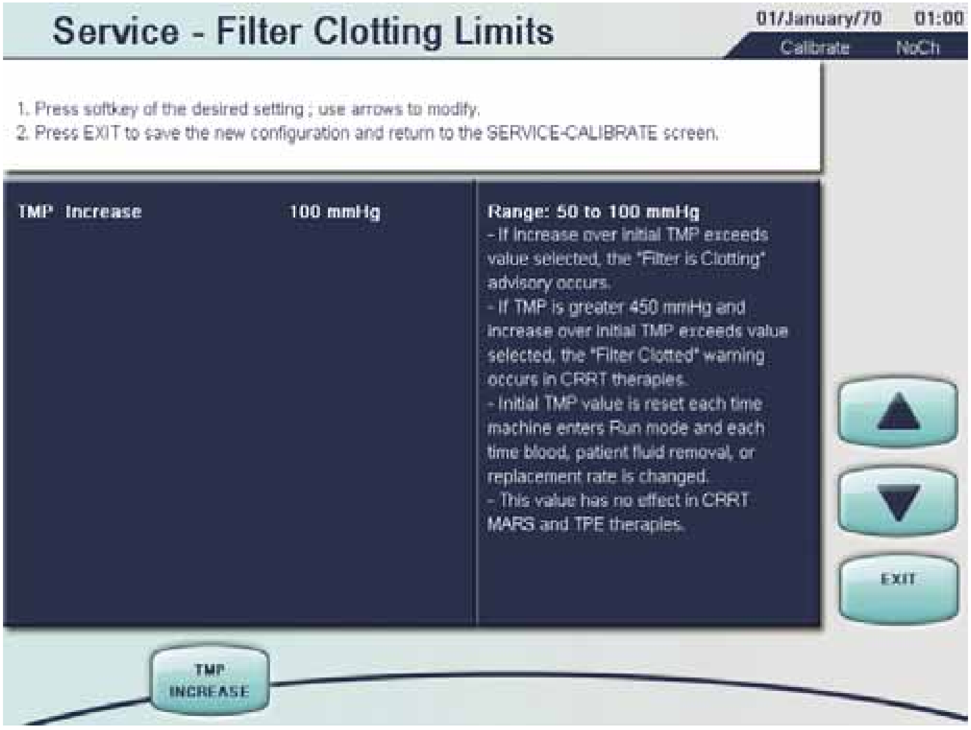
The `ADC value` represents the value read by the syringe pump (AD Converter) when a weight is applied. The `ADC value` is displayed on the screen.

The syringe pump slave uses an AD Converter with 10 bits so the `AD value` can assume values between 0 and 1023. If the value read from the pump at the first calibration point is outside the valid interval, the message `Syringe pump out of tolerance, can not be calibrated` appears on the screen. In this case the pump is damaged and must be replaced.

If the value read from the pump at the second calibration point is outside the valid interval, most probably a wrong calibration weight is used, and both the message;
`Calibration failed.  Check weight on plunger and retry` appears on the screen, and a new softkey *RETRY* becomes available. Before pressing the *RETRY* softkey, check that the correct

weight is used and that the correct weight value is entered on the screen. The calibration coefficients are calculated inside the slave with the 2 AD values read.

Calibration Screen – Filter Clotting Limits



In this screen it is possible to adjust filter clotting limits, by changing the value of the `TMP Increase` (Trans Membrane Pressure). The TMP determines when the Advisory “Filter Clotting” occurs.
The TMP value is calculated by;
TMP = TMPinitial + TMPincrease

Set the Filter Clotting Limits

1. Press the *TMP INCREASE* softkey.

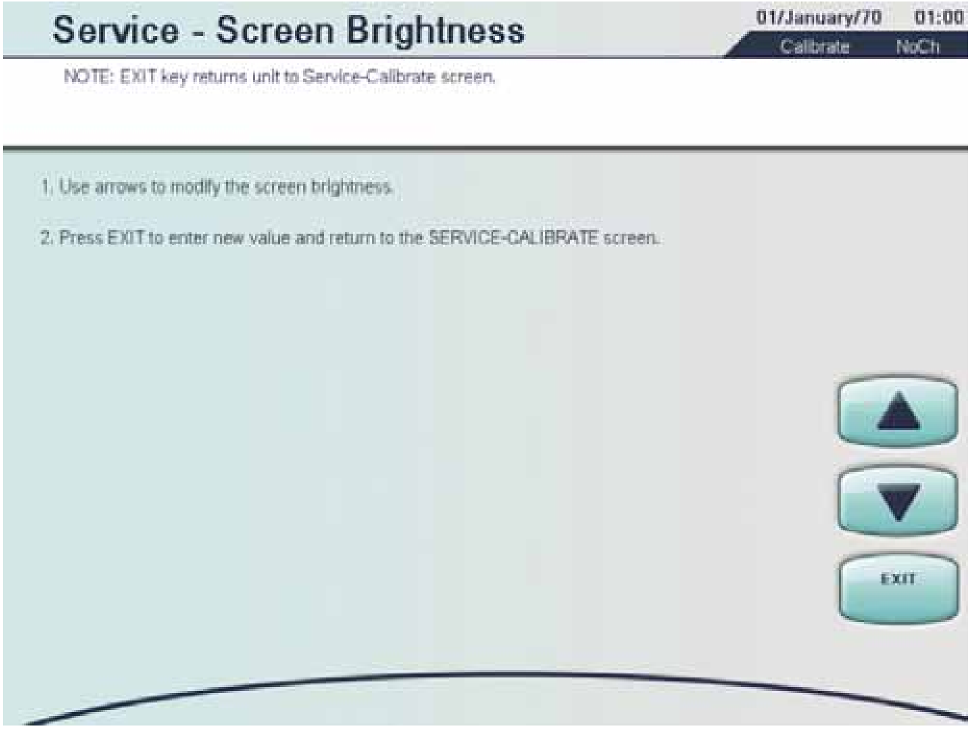
2. Use the *UP/DOWN ARROW* softkeys to modify the value;
   low flow filters: 50–100 mmHg
   high flow filters: 50 –80 mmHg

Calibration Screen – Set Clock and Date

Set the Clock and Date

1. Press the softkey corresponding to the parameter to be changed.
2. Use the *UP/DOWN ARROW* softkeys to adjust the displayed value.
3. The *DISPLAY ORDER* softkey changes the way the current date is displayed: `day/month/ year` or `month/day/year`

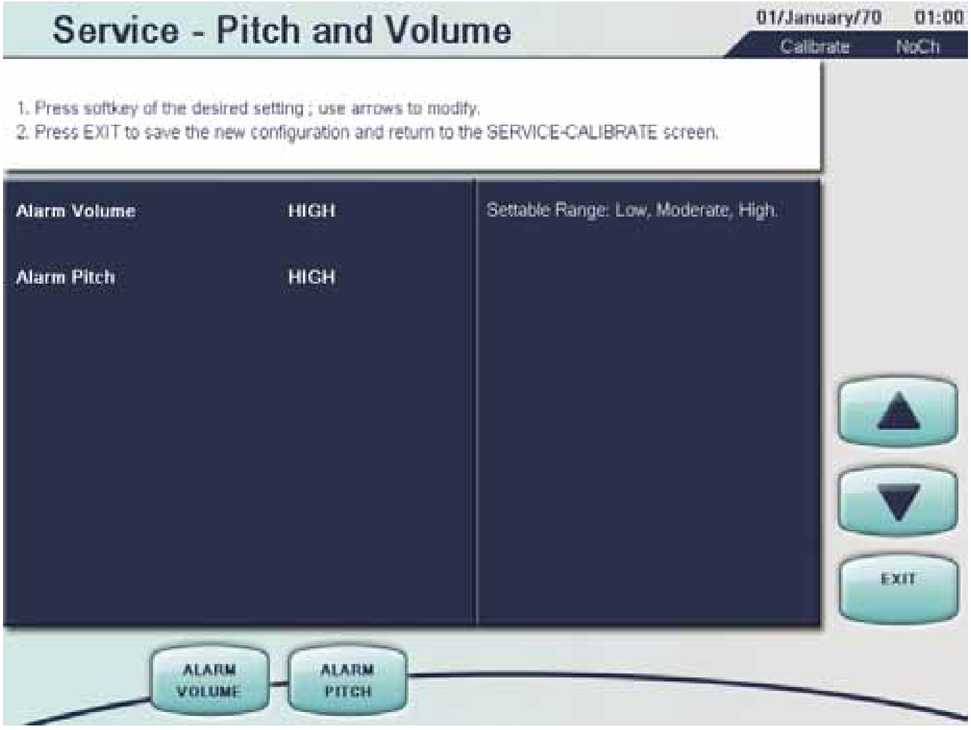
Calibration Screen – Screen Brightness Calibration



Set the Screen Brightness

Use the *UP/DOWN ARROW* softkeys to modify the screen brightness.

Calibration Screen – Pitch and Volume



Set the volume and alarm tone to one of the following values: LOW, MODERATE or HIGH.

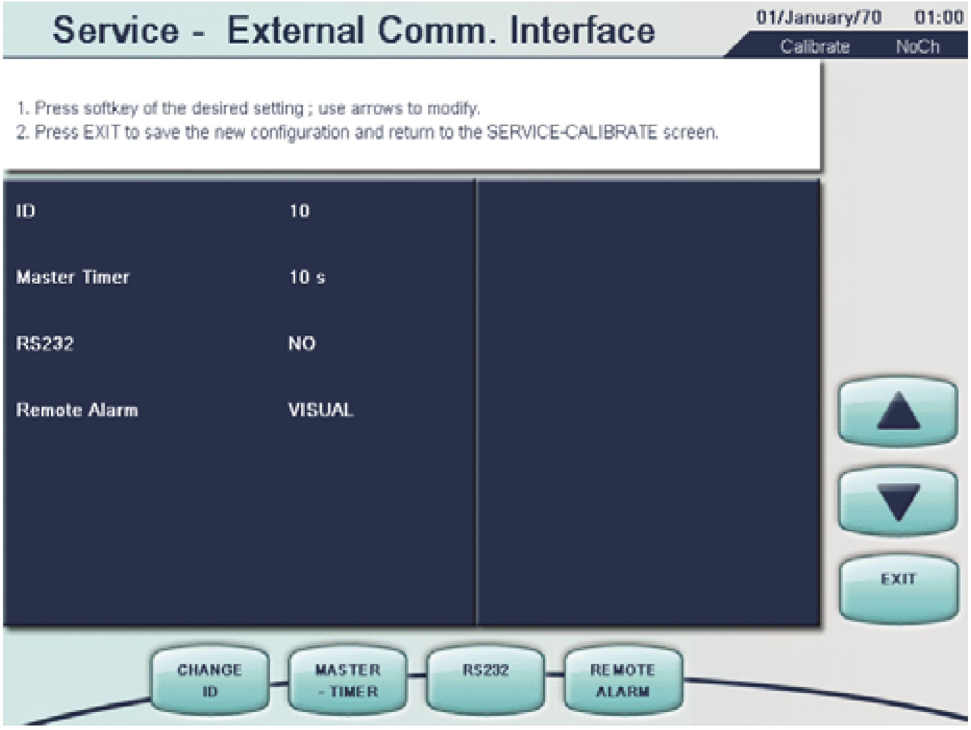
Default values are:

- Alarm Volume = HIGH
- Alarm Pitch = HIGH

Set the Pitch and Volume

1. Press the softkey of the desired setting.
2. Use the *UP/DOWN ARROW* softkeys to modify the setting.

Calibration Screen – External Communication Interface



Set the parameters related to the external communications.

- `ID`: this parameter is the setable Prismaflex control unit identity; a numerical value between 0 to 255 can be entered.
- `Master Timer`: this is the time between two subsequent transmissions in a one-way protocol. The time is selectable in the range between 5 to 60 seconds.
- RS232 = this parameter is used to enable or disable the RS232 communicator.
- `Remote Control`: displays the Remote Control label. The options associated with the Remote Control label can be either visual or auditory.

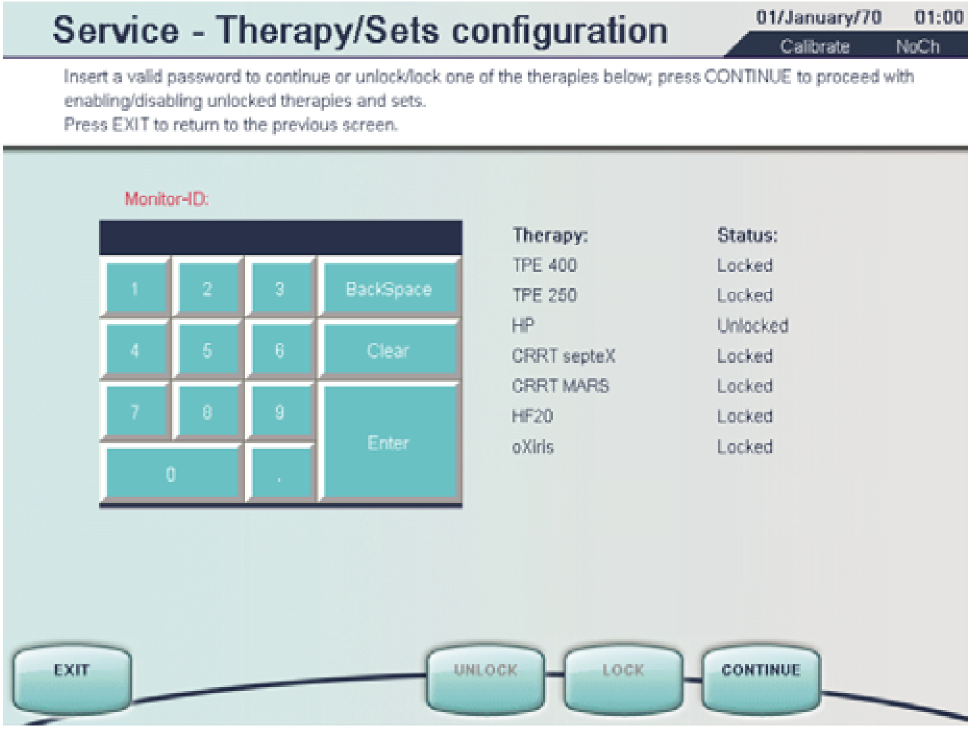
Default values

- `ID` = 10
- `Master Timer` = 10 seconds
- `RS232` = `NO` (disabled)

Configure the External Communication Interface

1. Press the softkey of the desired setting.
2. Use *UP/DOWN ARROW* softkeys to modify the setting.

Calibration Screen – Therapy/Sets Configuration



On the `Therapy/Sets Configuration` screen it is possible to unlock/lock different therapies. To unlock a therapy a password is required (different passwords for different therapies). The password is provided by Gambro Support, based on the Monitor ID (shown on the screen above) and on which therapy to be unlocked. All the therapies on the screen are locked by default.

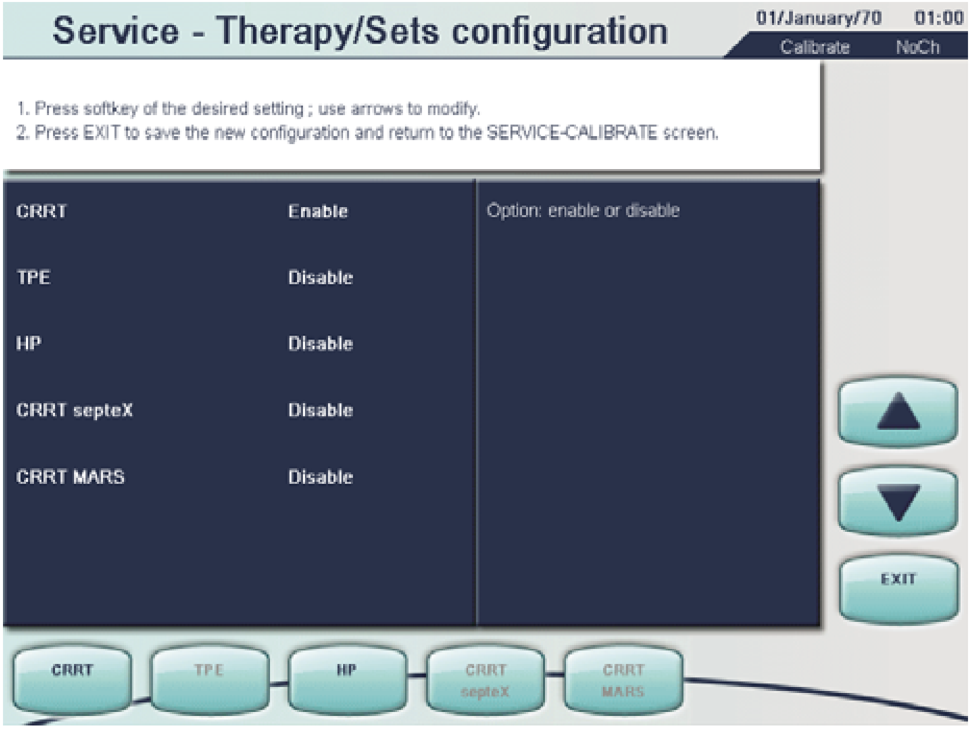
Configure the Therapy

1. Enter the password for the therapy to be unlocked, press *ENTER*.

2. The therapy, the *UNLOCK* softkey and *CONTINUE* softkey are activated.

3. Unlock the therapy. Repeat 1–3 to unlock several therapies.

4. Press *CONTINUE* to proceed with enabling/disabling therapies. A new screen appears.



Configure the Set

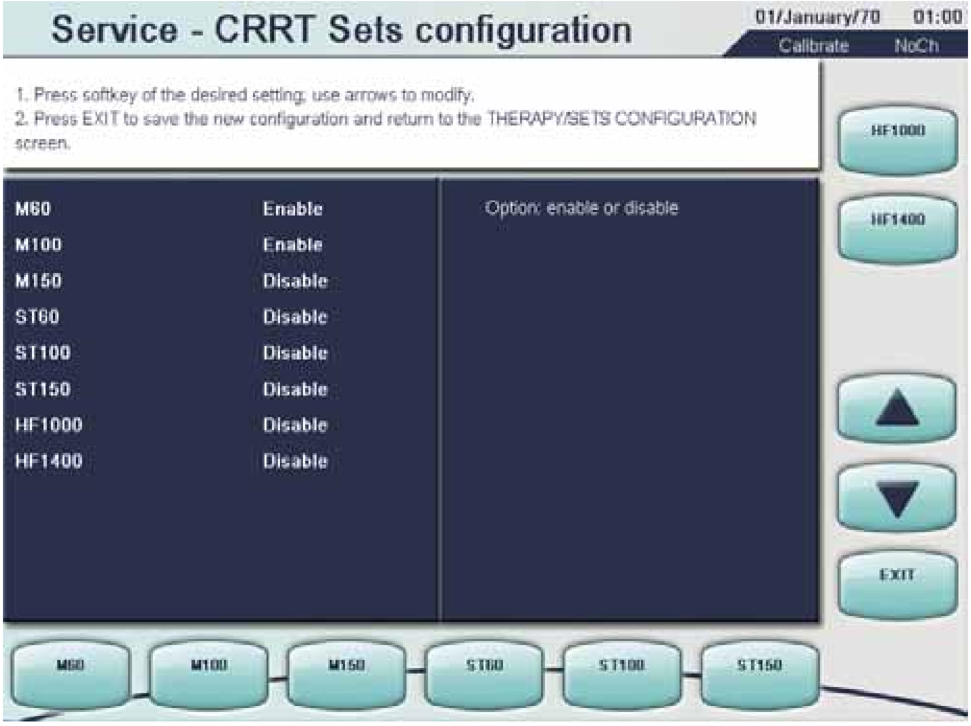
Note: Before enabling a set in the `Service - CRRT Sets configuration` screen, verify that the selected disposable set has been registered and can be sold in your own country.

1. Press the therapy to `Enable` (only the therapies that are unlocked are activated in the bottom of the screen), use *UP/DOWN ARROW* softkeys to modify.

2. When a therapy is selected, the therapy *SETS* softkey is activated.

3. Press the chosen therapy *SETS* softkey. A new screen appears.

Note: For HP, there is a *HP CARTS* (HP cartridges) softkey instead of a *SETS* softkey.

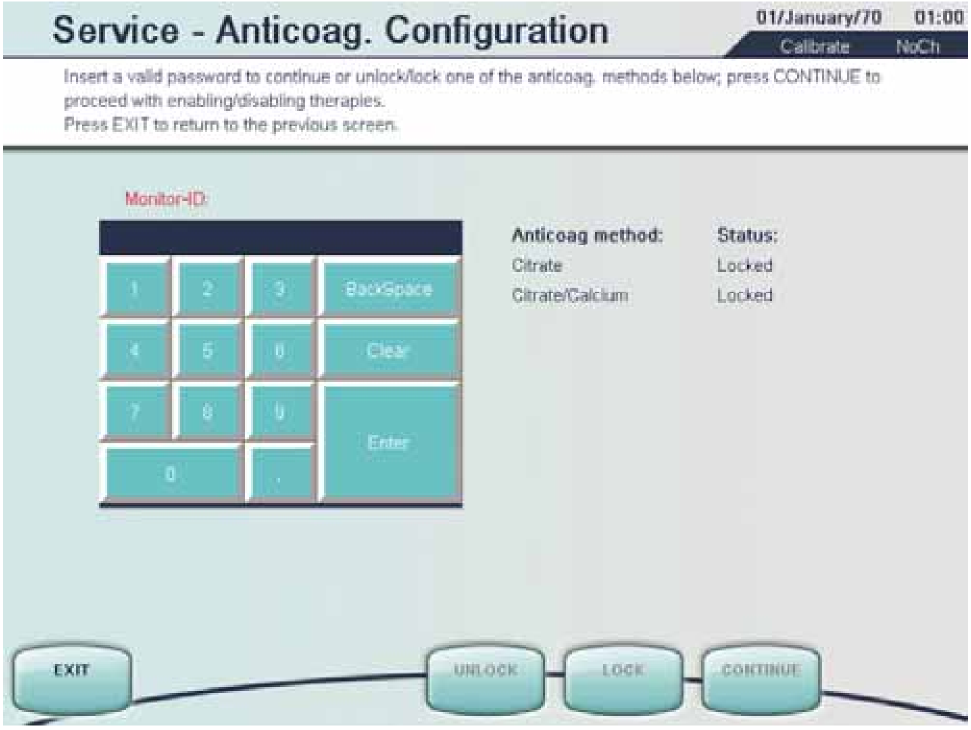


4. Press the softkey of the desired set(s) to `Enable`/`Disable`. Use the *UP/DOWN ARROW* softkeys to modify.

5. Press *EXIT* to save the new configuration and return to the `Service - Therapy/Set Configuration`.

Note: For HP, `Enable`/`Disable` the desired HP cartridge(s). Enabling Adsorba 150 or Adsorba 300 will enable both the Adsorba set and the HP-X set. Enabling user defined HP cartridges will enable the HP-X set.

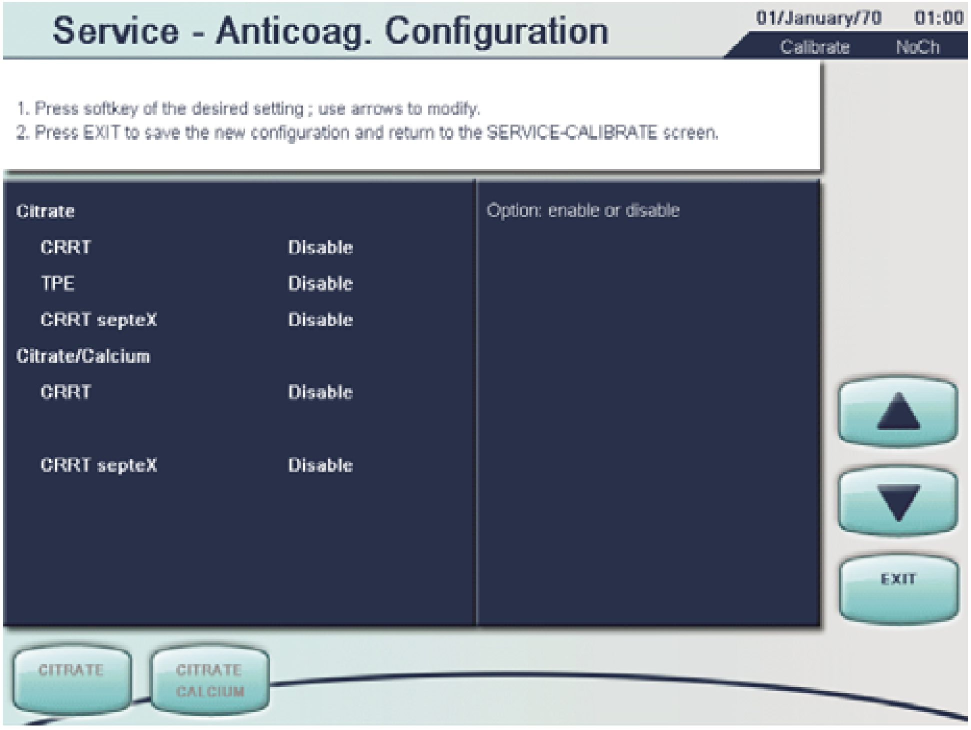
Calibration Screen – Anticoagulation Configuration



On the `Anticoagulation Configuration` screen it is possible to unlock the anticoagulation methods `Citrate` or `CitrateCalcium`. To unlock the methods a password is required. The password is provided by the Gambro Support and based on the `Monitor ID` (shown on the screen above) and the method intended to unlock.

Configure the Anticoagulation

1. Enter the password for the therapy to be unlocked, press *ENTER*
2. The method and the softkeys *UNLOCK* and *CONTINUE* are activated.
3. Unlock the method. Press *CONTINUE*. A new screen appears.

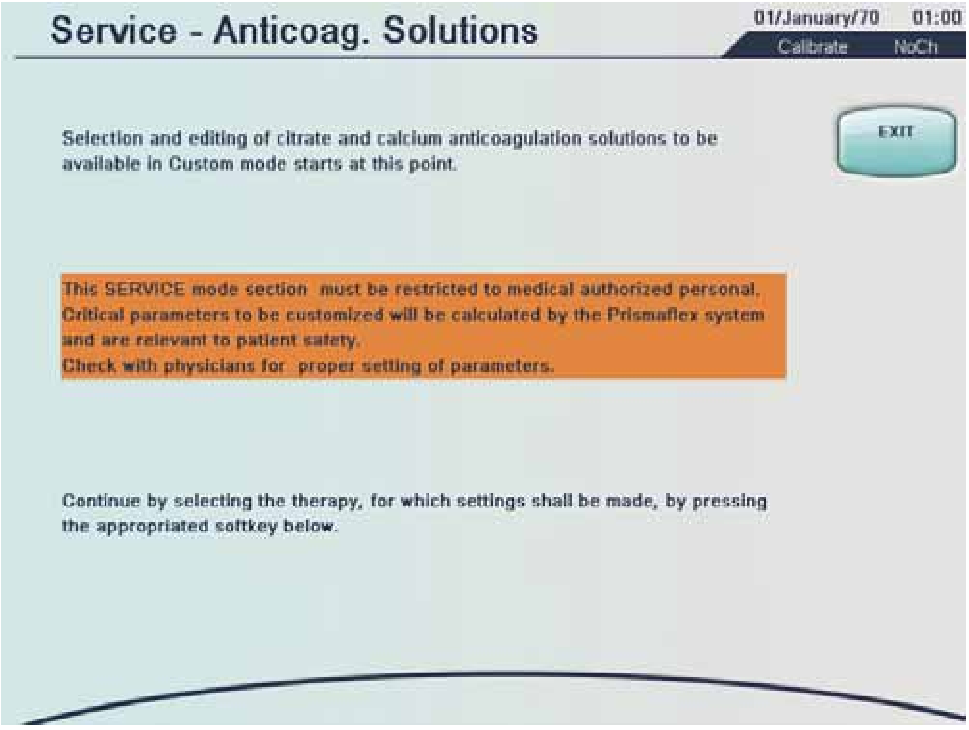


4. Choose the *CITRATE* or the *CITRATECALCIUM* softkey.

5. Press the therapy softkey to `Enable/Disable`. Use *UP/DOWN ARROW* softkeys to modify.

6. Press *EXIT* to save the new configuration and return to the `Service - Therapy/Set Configuration`.

Calibration Screen – Anticoagulation Solutions



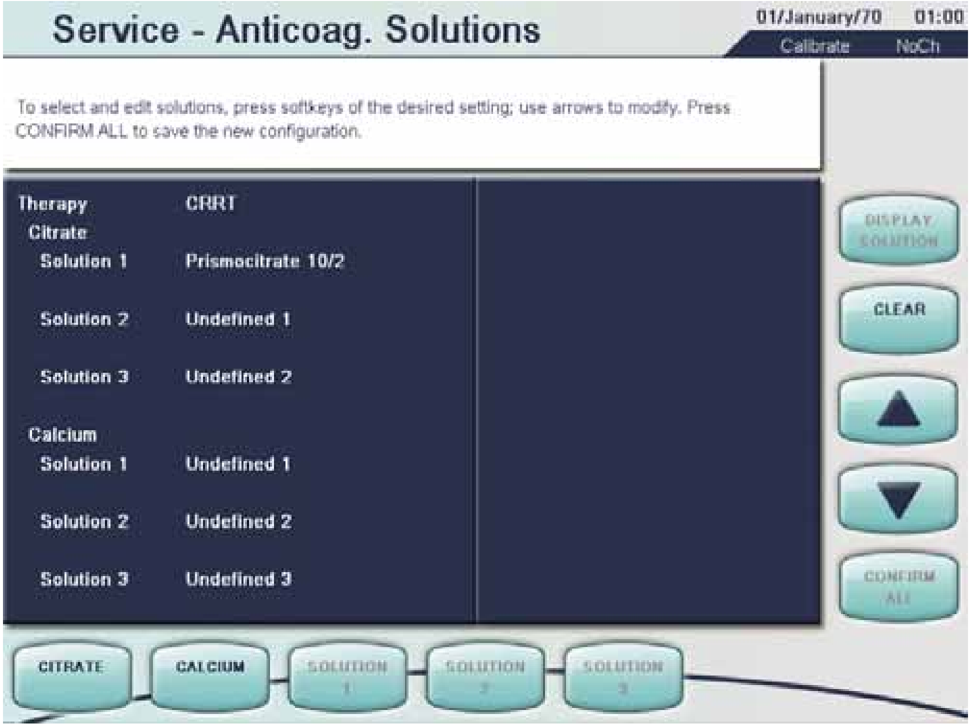
CAUTION

This Service mode section must be restricted to medical authorized personal. Critical parameters to be customized will be calculated by the Prismaflex system and are relevant to the patient safety. Check with physicians for proper setting of parameters.

CAUTION

Configure the Anticoagulation Solutions

1. Select the therapy for setting (only the enable therapies are selectable), by pressing the softkeys at the bottom of the screen. A new screen appears.



2. Chose the *CITRATE* or the *CALCIUM* softkey.

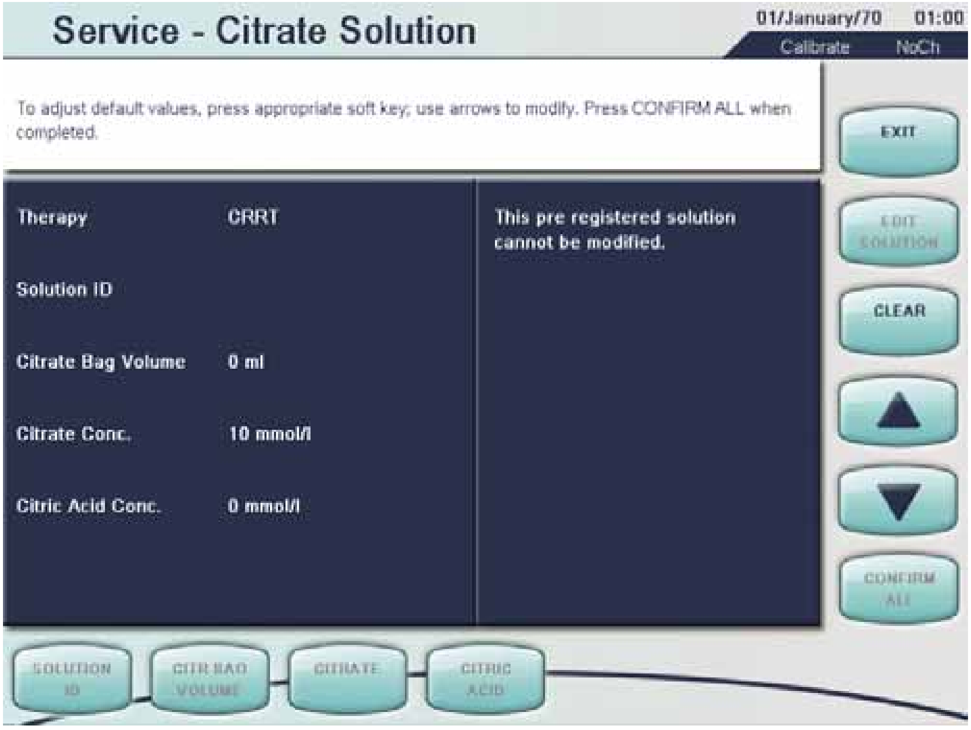
CITRATE

3. When the *CITRATE* softkey is pressed, the softkeys *SOLUTION 1, 2, 3* are activated.

4. For each *SOLUTION* softkey it is possible to make five different settings, one default and four undefined.

5. Press one of the softkeys *SOLUTION 1, 2, 3*, choose default or undefined setting, using the *UP/DOWN ARROW* softkeys. When the *SOLUTION 1, 2, 3* is pressed the *DISPLAY SOLUTION* softkey is activated.

6. The *DISPLAY SOLUTION* softkey opens a new screen where it is possible to view and edit the solution composition.



7. If needed, press the *EDIT SOLUTION* softkey to edit the solution. The default setting is not editable.

8. The softkeys *SOLUTION ID*, *CITR BAG VOLUME*, *CITRATE* and *CITRIC ACID* is activated and it is possible to edit the solution.

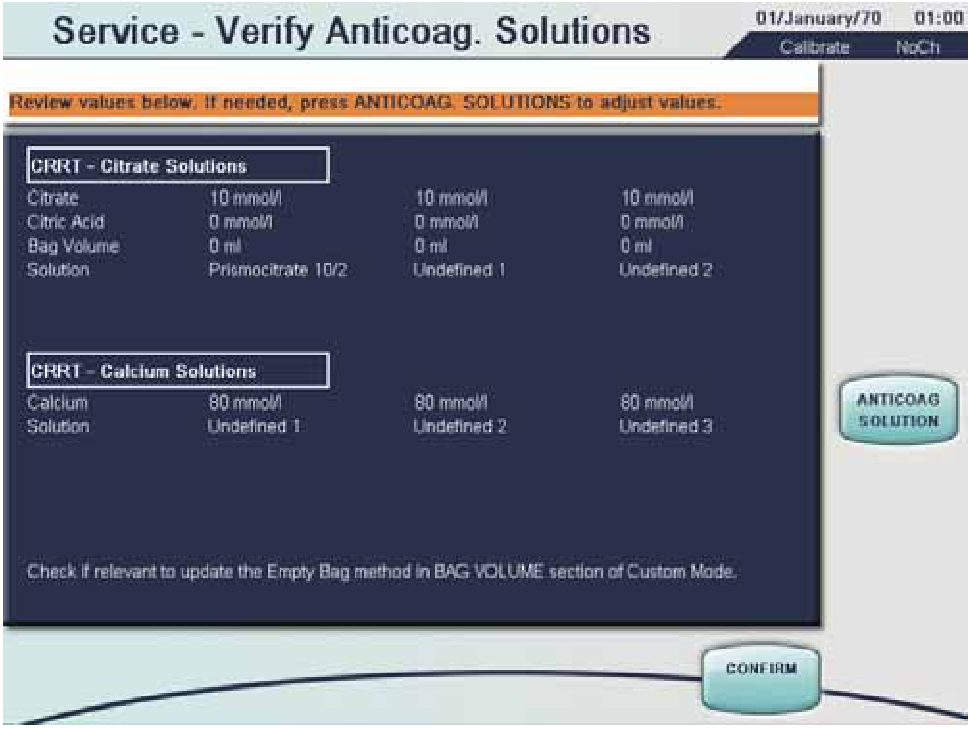
Note: There are different ranges available for different available therapies.

9. Adjust the settings, use the *UP/DOWN ARROW* softkeys to modify. Press *CONFIRM ALL* when adjustment is completed.

10. If needed, repeat 3 - 11 for each of the *SOLUTION 1,2,3* softkeys.

11. Press *CONFIRM ALL* to save the new configuration.

12. The screen `Verify Anticoag. Solutions` appears.



13. Review the values on the screen. If needed, press the *ANTICOAG. SOLUTIONS* softkey to adjust values.

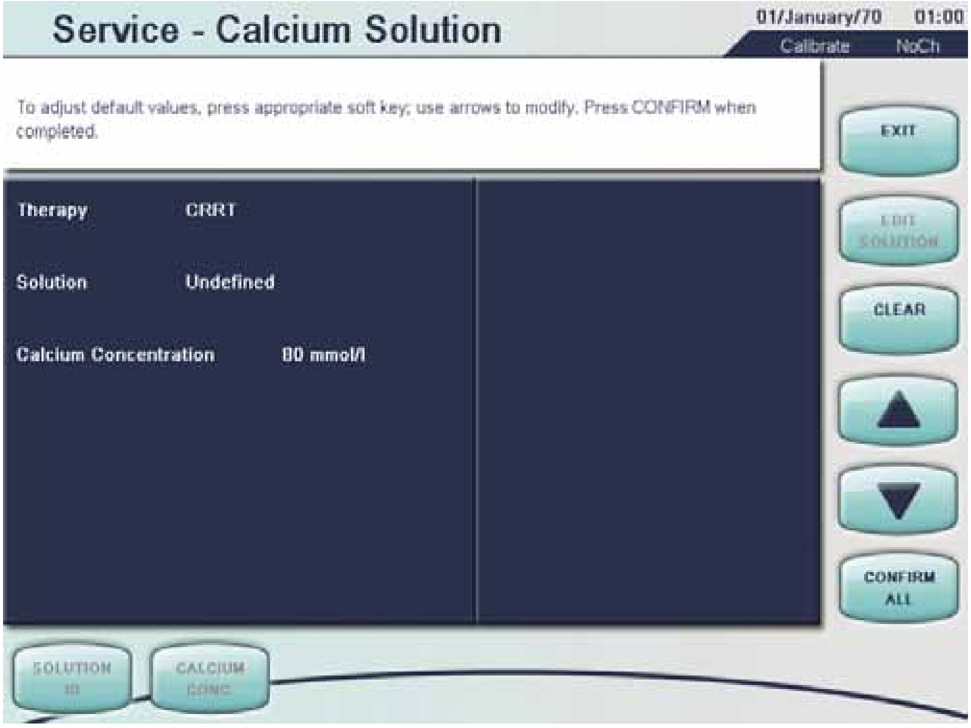
CALCIUM

14. When the *CALCIUM* softkey is pressed, the softkeys *SOLUTION 1, 2, 3* are activated.

15. For each *SOLUTION* softkey it is possible to make five editable settings.

16. Press one of the softkeys *SOLUTION 1, 2, 3*, use *UP/DOWN ARROW* softkeys to modify.

17. When the *SOLUTION 1, 2, 3* is pressed the *DISPLAY SOLUTION* softkey is activated. The *DISPLAY SOLUTION* softkey opens a new screen where it is possible to view and edit the solution composition.



18. If needed, press the *EDIT SOLUTION* softkey to edit the solution composition.

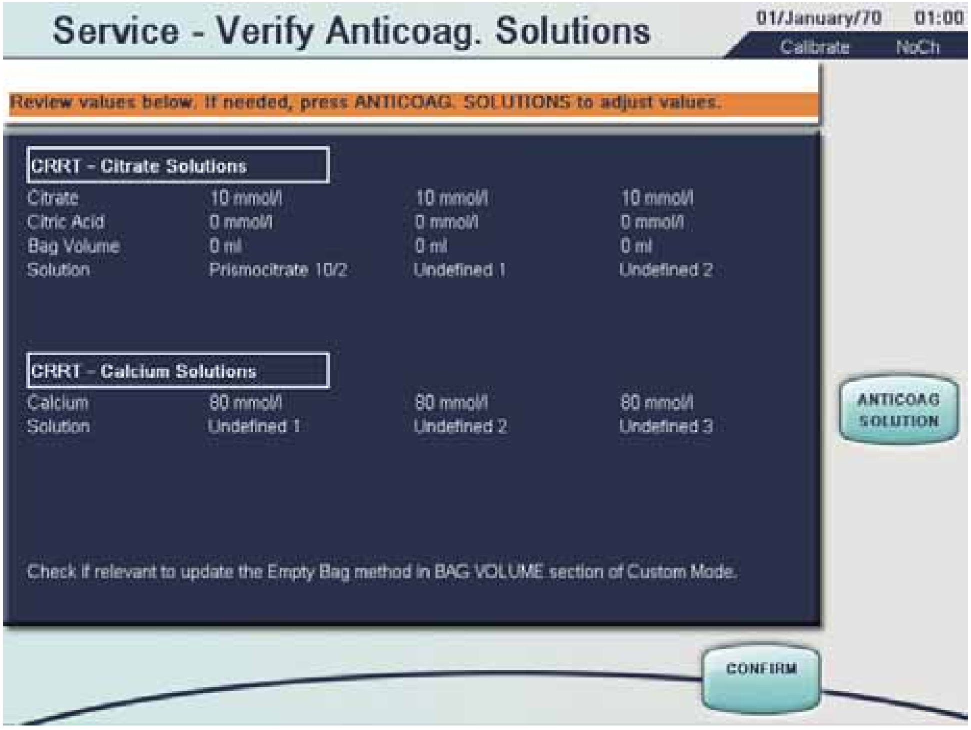
19. The softkeys *SOLUTION ID*, and *CALCIUM CONC.* are activated and it is possible to edit the solution.

20. Adjust the settings, use the *UP/DOWN ARROW* softkeys to modify. Press *CONFIRM ALL* when adjustment is completed.

21. If needed, repeat 14 - 21 for each of the *SOLUTION 1,2,3* softkeys.

22. Press *CONFIRM ALL* to save the new configuration.

23. The screen `Verify Anticoag. Solutions` appears.

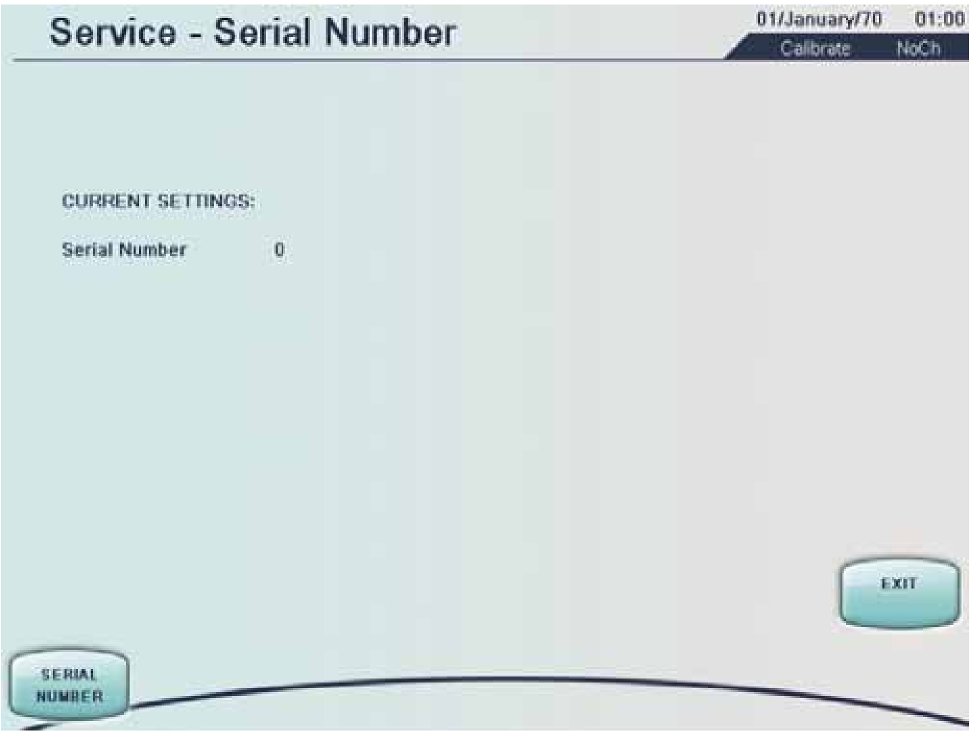


24. Review the values on the screen. If needed, press the *ANTICOAG. SOLUTIONS* softkey to adjust values.

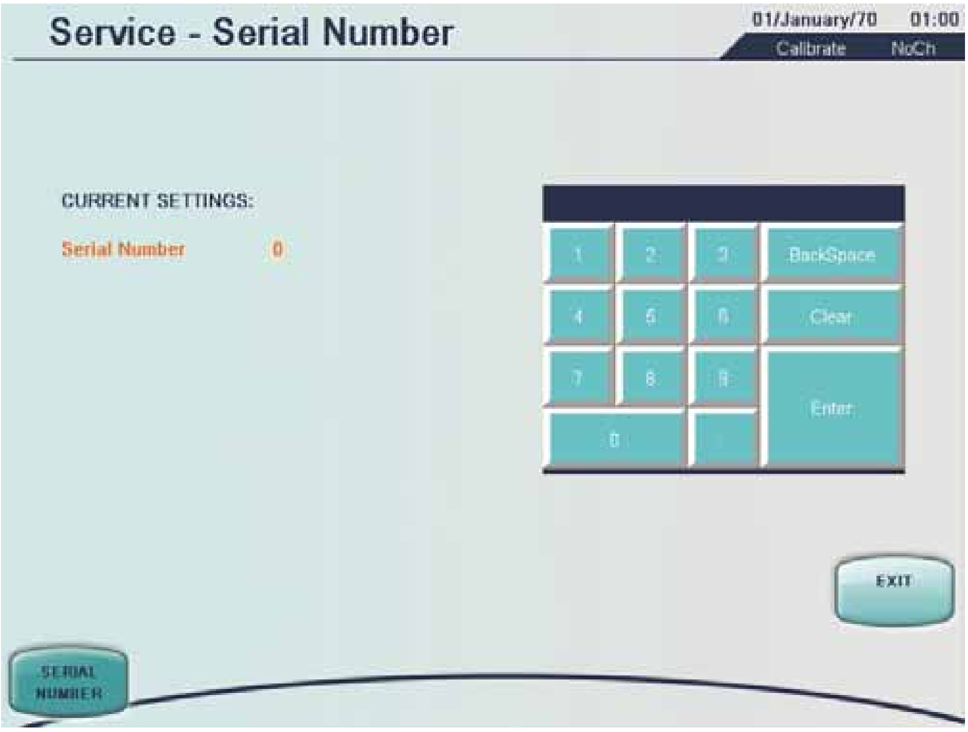
Calibration Screen – Serial Number

Change Serial Number

The current entry for the Serial Number is displayed.



1. Press the *Serial Number* softkey.

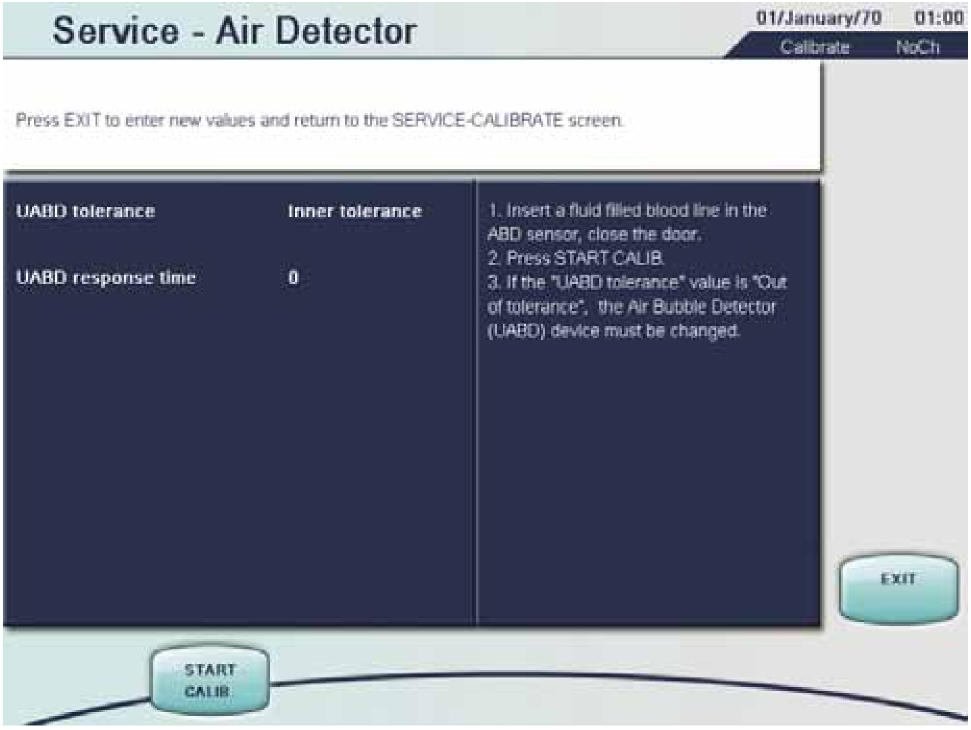


2. Use the soft key numbers to enter the serial number found at the label at the back of the machine. Some Control units have letters before the serial number on the type label and they are not entered.

3. Press Enter

Note: The entry for serial number is deleted (set to zero) during a software update.

Calibration Screen – Air Detector



Tools needed: Prismaflex disposable set return line tube filled with fluid.

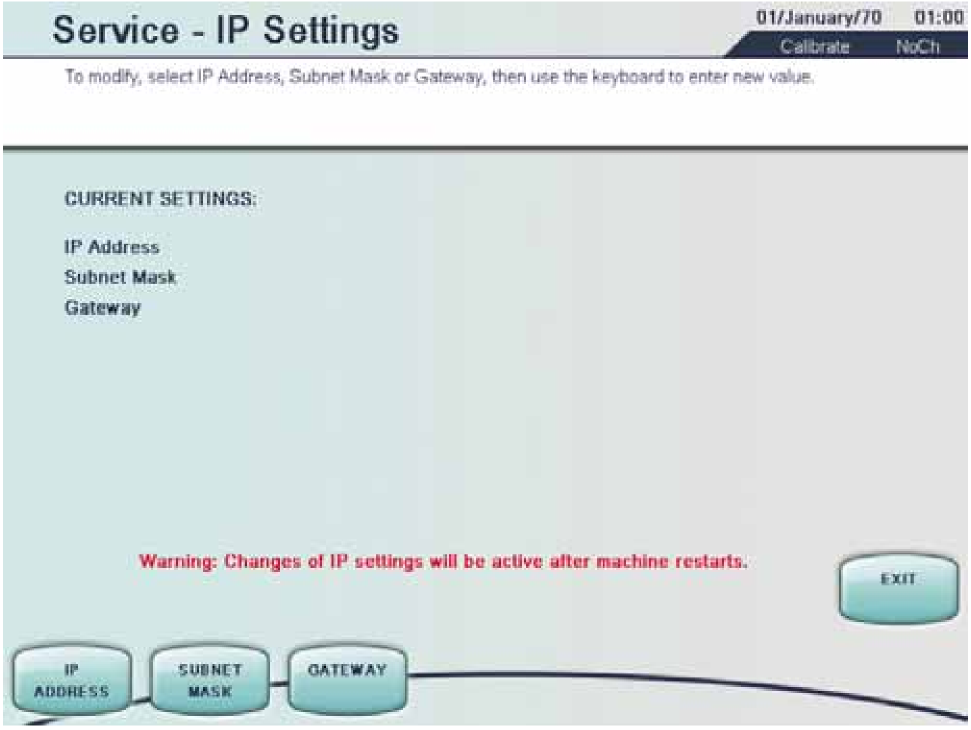
Calibrate the Air Detector

1. Insert a fluid filled blood line in the ABD sensor, close the door.

2. Press the *START CALIB.* softkey.

3. If the `UABD tolerance` value is `Out of tolerance`, the Air Bubble Detector (UABD) must be replaced.

Calibration Screen – IP Settings

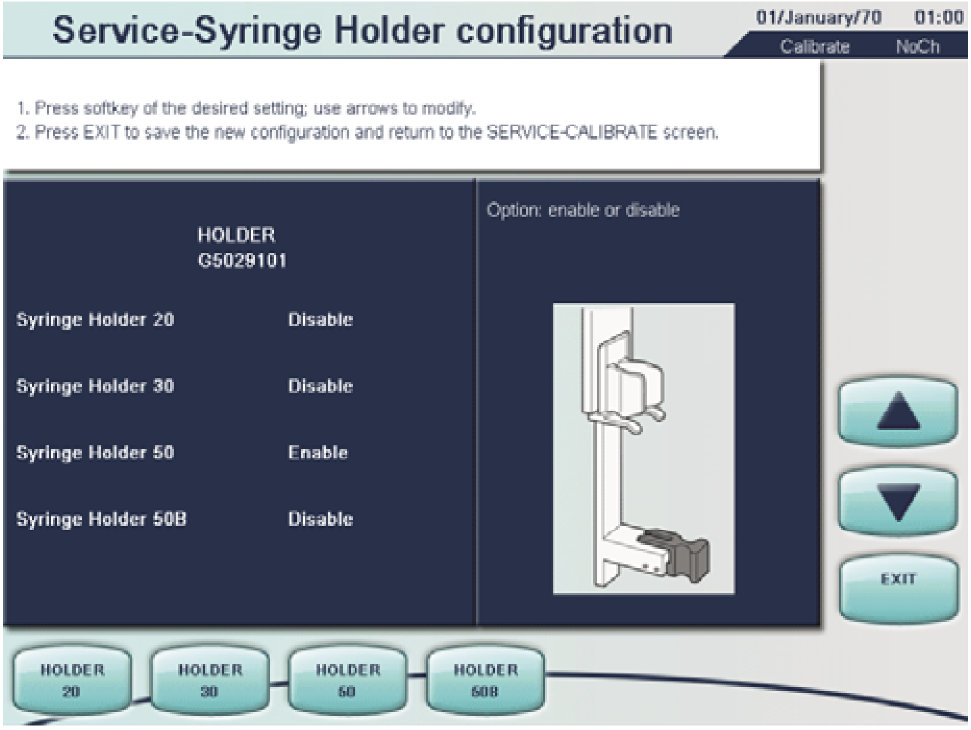


Note: Changes about `IP address` and/or `Subnet Mask` will be active after the Prismaflex control unit restarts.

Set the IP Address/Subnet Mask/Gateway

1. Press the softkey of the desired setting.
2. Use the numerical keyboard. Press *ENTER* softkey to store new value.

Calibration Screen – Syringe Holder Configuration

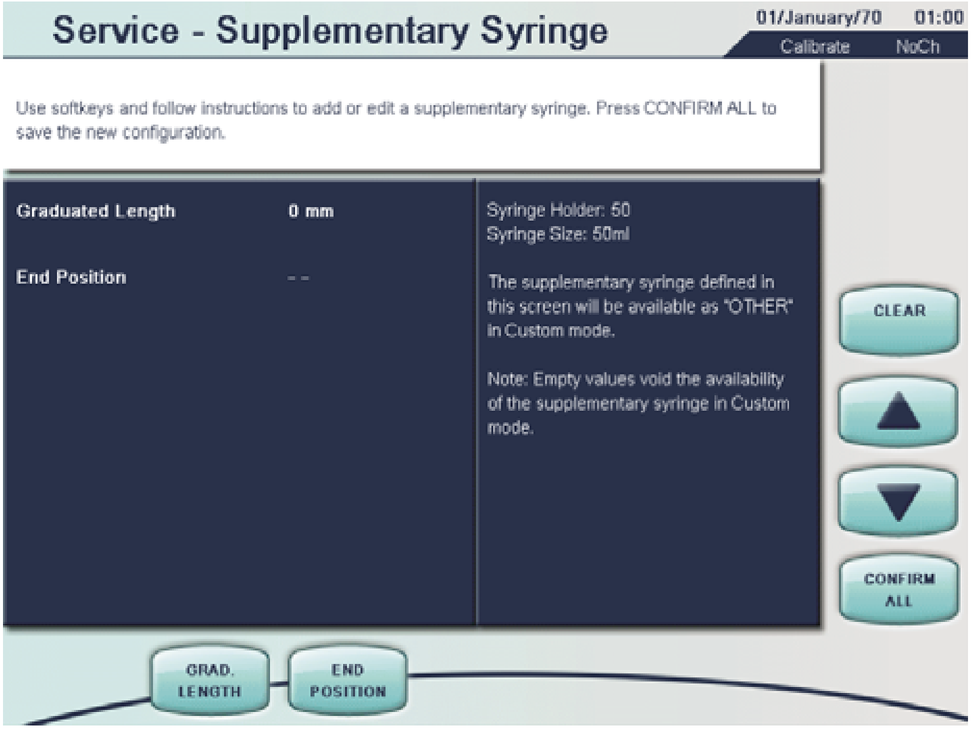


The configuration must be performed by an authorized service technician.

Configure the Syringe Holder

1. Press the softkey of the desired setting.
2. Use *UP/DOWN ARROW* softkeys to modify.

Calibration Screen – Supplementary Syringe

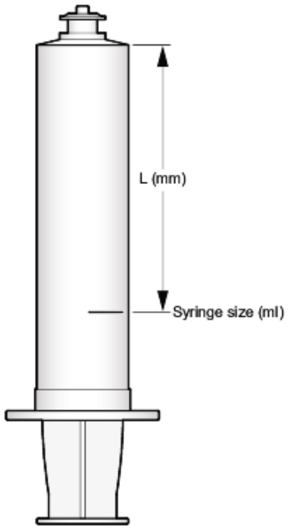


Configure the Supplementary Syringe

1. Press the softkey of the desired setting and follow the instructions.

Graduated Length

Measure and enter the length between graduation marks that correspond to the `Syringe Size` (e.g. the distance between 0 ml and 50 ml if the size of the syringe is 50 ml). Use *UP/DOWN ARROW* softkeys to set the value.

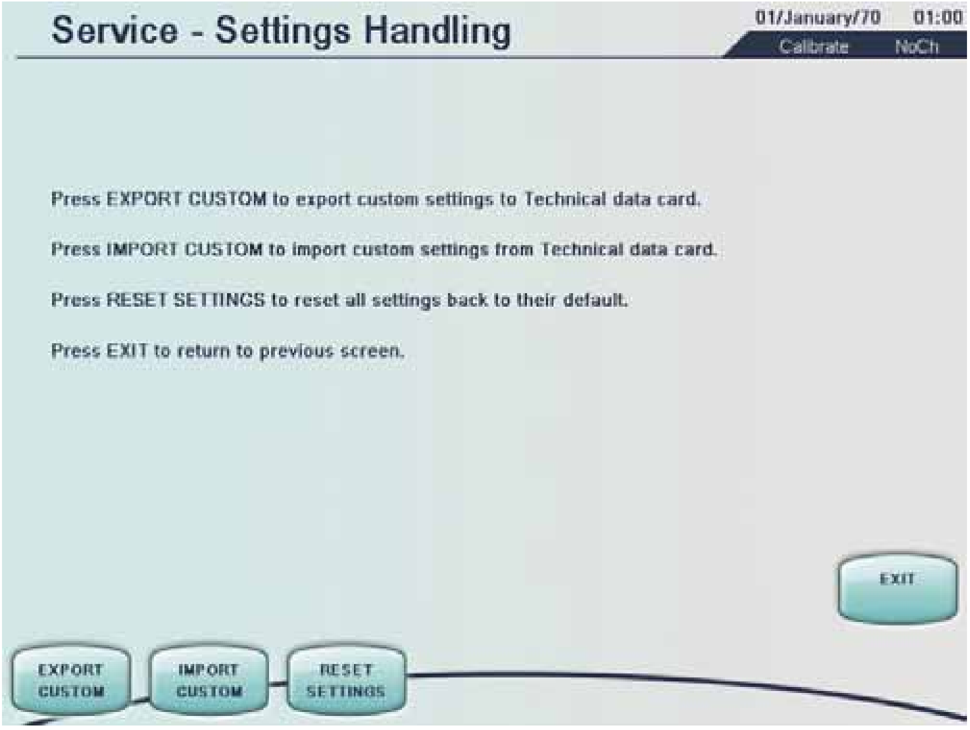


End Position

Open the plunger clamp latch and press the *MOVE DOWN* softkey.
Place the syringe in the holder, insert its wings into the holder's slot.
Press the *MOVE UP* softkey.
Verify that the `End Position` is displayed as `OK`.

2. Press the *CONFIRM ALL* softkey to confirm the settings and return to the `Service - Calibrate` screen.

Calibration Screen – Settings Handling



On the `Settings Handling` screen it is possible to export/import custom settings to/from the technical data card as well as to reset custom settings to manufacturer's default settings.

Custom settings can only be shared between Prismaflex control units with same SW revision and specific custom settings are imported only if custom settings are unlocked.

When upgrading several machines at a clinic, make sure that all machines have same custom settings unlocked. Thereafter enable disposable sets, blood warmer, customize anticoagulation solutions, customize HP cartridges and other custom settings. When all settings are made, use export customs settings and import settings on remaining Prismaflex control units. After restart of the Prismaflex control unit all custom settings are active.

Export Custom mode settings

1. Insert a technical data card in the holder on rear panel of the Prismaflex control unit.

2. Press *EXPORT CUSTOM* softkey.

3. Remove the technical data card.

Import Custom mode settings

1. Insert the technical data card in its holder on rear panel of the Prismaflex control unit.

2. Press *IMPORT CUSTOM* softkey.

3. Press *CONFIRM* softkey to proceed with the import or *CANCEL* softkey to return back to main screen.

4. Remove the technical data card.

5. Restart the Prismaflex control unit.

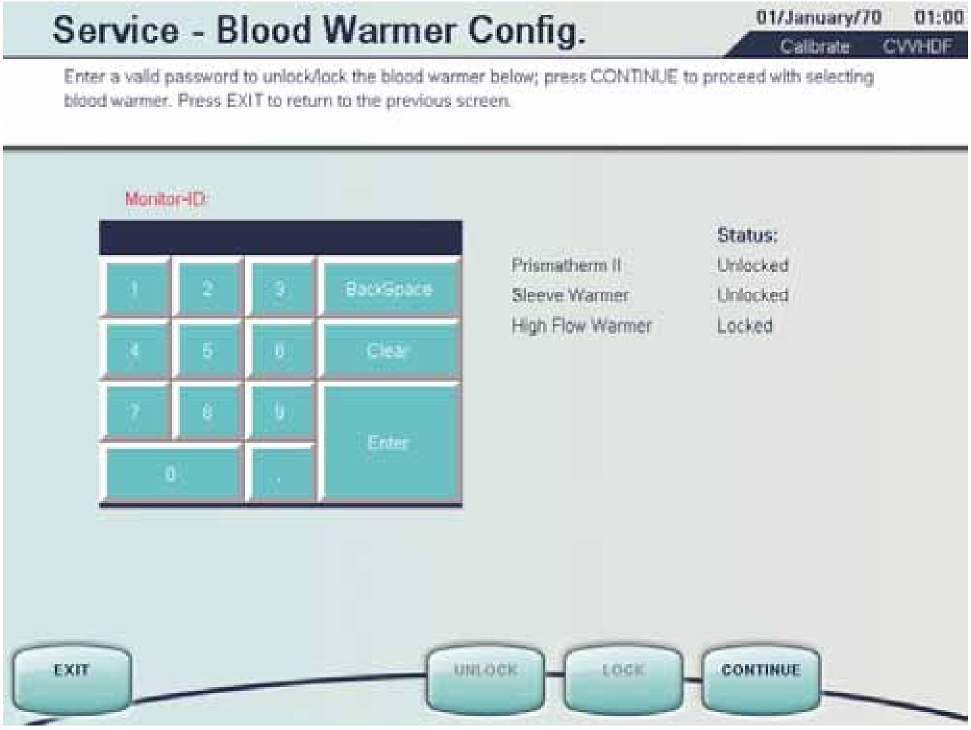
Reset Custom mode settings

1. Press *RESET SETTINGS* softkey.

2. Press *CONFIRM* to proceed with the reset back to manufacturer's default settings or *CANCEL* to return back to main screen.

3. Restart the Prismaflex control unit.

Calibration Screen – Blood Warmer Configuration

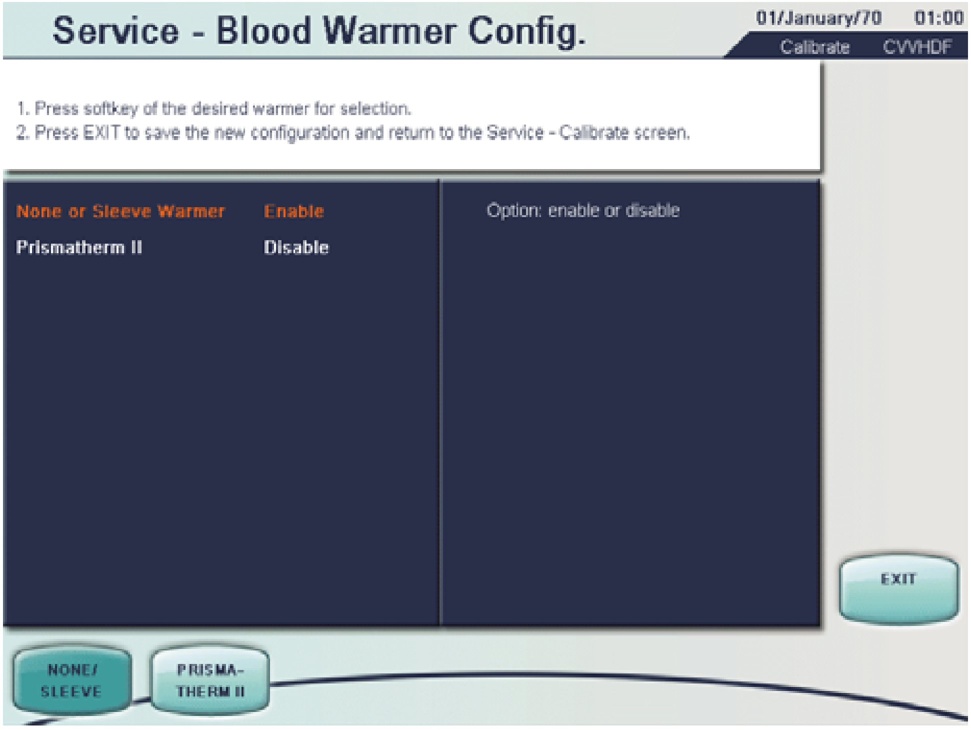


On the `Blood Warmer Configuration` screen, installed blood warmer shall be configured.

To unlock a blood warmer a password is required. The password is provided by the Gambro Support, based on the Monitor ID (shown on the screen above) and on which blood warmer to be unlocked. Prismatherm II and sleeve warmers are unlocked by default.

Configure the blood warmer

1. Enter the password for the blood warmer to be unlocked, press *ENTER*.
2. The blood warmer, the *UNLOCK* softkey and *CONTINUE* softkey are activated.
3. Unlock the blood warmer. Repeat 1–3 to unlock several blood warmers.
4. Press *CONTINUE* to proceed with enabling/disabling of unlocked blood warmers. A new screen appears.



5. Press the blood warmer to enable (only the blood warmers that are unlocked are activated in the bottom of the screen).

6. Press *EXIT* to save the new configuration.

Configuration will activate `Connect Blood Warmer` screen in Setup mode if the blood warmer needs to be included in the priming sequence.

Functional Test

Before releasing the Prismaflex control unit for use, perform the functional checkout procedure. The test is performed using saline solution as a substitute for priming, pre-blood, replacement and dialysate solutions, and a container, or bag of water as a substitute for the patient. Successful completion of the functional checkout indicates that the Prismaflex control unit is operating properly.

WARNING

A patient must not be connected to the Prismaflex System during the functional checkout. Be sure that the checkout is conducted using a container of water to substitute for the patient.
If a Malfunction alarm occurs during the functional checkout, the Prismaflex control unit has failed the checkout. Do not use the Prismaflex System until the problem has been corrected and the Prismaflex System has passed the checkout.

WARNING

Supplies needed:

- Prismaflex CRRT set
- 4 fluid bags (saline solution) 1000 ml each
- 1 fluid container 1000 ml, filled with 500 ml tap water

1. Turn on the Prismaflex control unit. The Prismaflex control unit performs an initialization test to check the system electronics, startup signal sounds twice and status lights (green, red and yellow) are lit during the test.
2. In the Prismaflex system screen, press the *CONTINUE* softkey. If the `Query` screen is displayed instead of the `Set-up` screen, select the *NEW PRIME* softkey and confirm it in the following screen.
3. Choose *NEW PATIENT* when the `Choose Patient` screen appears, confirm New Patient choice by pressing *CONTINUE* on the `Enter Patient Info` screen. Select the *CVVHDF THERAPY* softkey when the `Choose Therapy` screen appears.
4. Choose *NO ANTICOAGULATION* as anticoagulation method.
5. Follow the instructions on the screen to load and prime the Prismaflex disposable set. Use saline solution as a substitute to priming and dialysate solutions. The Prismaflex control unit performs multiple self-tests during the priming cycle.
6. When the prime and the prime test are completed, press *CONTINUE*. The `Enter Treatment Settings` screen appears. Set the Loss/Gain Limit to 140 ml/3h. Press *CONFIRM ALL*.

7. The `Enter Flow Settings` screen appears. Set the following flow rates and press the *CONFIRM ALL* softkey.

Blood: 180 ml/min	PBP: 1100 ml/h	Dialysate: 1200 ml/h	Replacement: 1300 ml/h	Fluid Removal Rate: 200 ml/h

8. When the `Review Prescription` screen appears, verify the above flow rates, then press *CONTINUE*.

9. When the `Connect Patient` screen appears, place the access and return lines preferably connected through an 8F catheter into the container of water. Press *CONTINUE*.

10. The `Verify Patient Connection` screen appears. Press the *START* softkey, to enter Run mode.

Note: Because the installation test is performed with water, the `Warning: Return Disconnection` and `Advisory: Cannot Detect Return` alarms could occur after the Prismaflex control unit has entered Run mode. If this alarms occurs, press *CONTINUE*/*OVERRIDE* (depending on active alarm) and continue with the test. The alarms will not affect the outcome of the installation test.

11. Note the hour and minute on the `Status` screen when the Prismaflex control unit enters Run mode (this information can be found in `History` screen, pressing *Events* softkey).

12. Let the Prismaflex control unit run for at least 15 minutes.

13. Place a clamp on the access line (red) below the cartridge. The `Warning: Access Pressure Extremely Negative` alarm should occur. Verify that the red light is flashing and the audible alarm sounds with a high sound, 10 sound pulses repeated approx. every 8 seconds.

14. Unclamp the access line and press the *CONTINUE* softkey on the `Warning` screen. Verify that the alarm is cleared (Warning screen leaves display, green light is lit).

15. Check the Battery Backup function.
Note: Performed only if the Prismaflex control unit has Battery Backup installed. See section “Third Technical Screen” on page 4:32, Power section. Otherwise continue with step 19.
Disconnect the power cord from the wall socket. The `Advisory: Main Power Lost` alarm should occur. Verify that the yellow light is permanently lit and the audible alarm sounds with a low sound, 2 sound pulses repeated approx. every 21 seconds.

16. Press the *OVERRIDE* softkey. The `Advisory` screen leaves the display, but remains in Examine Alarms. Yellow light is lit, the Prismaflex control unit returns to the Status screen and the battery icon, in the top right corner of the display, is lit.

17. Connect the power cord to the wall socket. Verify that the battery icon disappears and that the Prismaflex control unit continues in run mode. Verify that the alarm is cleared from the Examine Alarms (press *SYSTEM TOOLS* softkey and verify that the *EXAMINE ALARMS* softkey is not present) and green light lit.

18. Press the *STOP* softkey, then press the *END TREATMENT* softkey and follow the instructions to unload the set.

Final Check

1. Verify update of PM intervention in the `Service Diagnose` screen on the Prismaflex control unit.

2. Fill in the PM sticker and apply to the Prismaflex control unit.

3. Document the service in the Log Book of the Prismaflex control unit and in the service report system. Together with the service report, document the Prismaflex control unit configuration with either of the following:

   - Download the logging data of the simulated treatment (LOX file) from the technical data card, and attach it to the GFS record.

   - Download the logging data of the simulated treatment (LOX file) from the technical data card, and email it to barcode@gambro.com.

   - Take a photo of the barcode in Service mode according to instructions in Service - Diagnose, 2D Barcode, and send it to barcode@gambro.com.

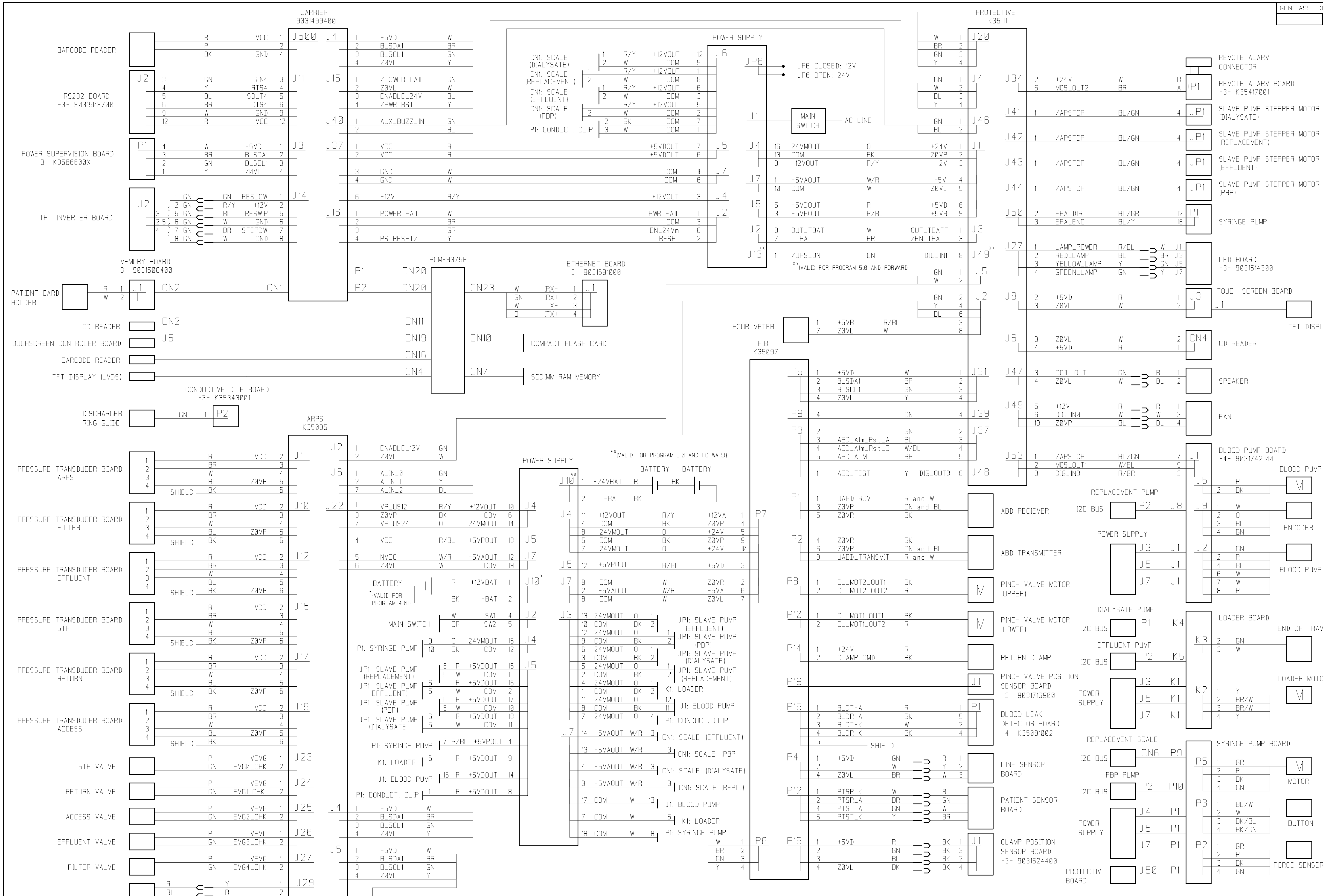
Verify that the Preventive Maintenance checklist is filled in. File a copy of the checklist with the appropriate hospital and manufacturer/distributor personnel.

This page is intentionally left blank

Chapter 7

Schematics

The following pages shows wiring diagrams over the Prismaflex control unit with all internal connections between the different subunits.



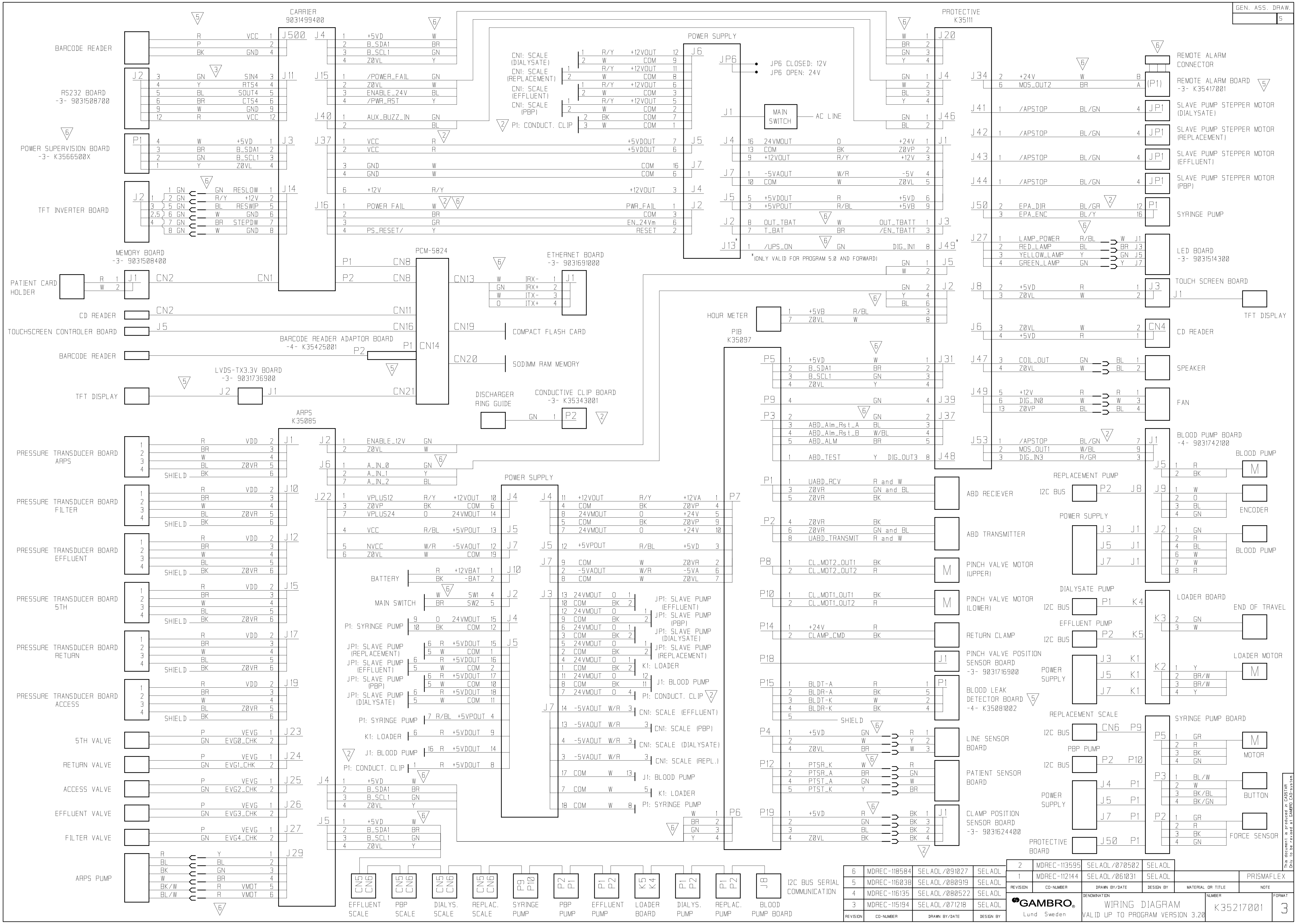
GEN. ASS. DRAW.
5

1	MDREC-118584	SELAOL/091027	SELAOL		PRISMAFLEX
REVISION	CO-NUMBER	DRAWN BY/DATE	DESIGN BY	MATERIAL OR TITLE	NOTE

GAMBRO Lund Sweden

DENOMINATION: WIRING DIAGRAM VALID FROM PROGRAM VERSION 4.01

NUMBER: K60282001 FORMAT: 3



REVISION	CO-NUMBER	DRAWN BY/DATE	DESIGN BY
6	MDREC-118584	SELAOL/091027	SELAOL
5	MDREC-116038	SELAOL/080919	SELAOL
4	MDREC-115135	SELAOL/080522	SELAOL
3	MDREC-115194	SELAOL/071218	SELAOL
2	MDREC-113595	SELAOL/070502	SELAOL
1	MDREC-112144	SELAOL/061031	SELAOL

MATERIAL OR TITLE: PRISMAFLEX

GAMBRO Lund Sweden

DENOMINATION: WIRING DIAGRAM
VALID UP TO PROGRAM VERSION 3.20

NUMBER: K35217001

FORMAT: 3

Chapter 8
Specifications

Contents

Performance . . . 8:3
Flow Rates and Accuracy . . . 8:3
Blood Flow Rate . . . 8:3
Automatic Blood Return Volume . . . 8:3
Replacement Solution/Fluid Flow Rate . . . 8:3
Dialysate Flow Rate . . . 8:3
PBP Solution Rate . . . 8:4
Patient Fluid Removal Performance / Patient Plasma Loss Performance . . . 8:4
Effluent Flow Rate . . . 8:4
Syringe Settings . . . 8:5
Systemic, Prismaflex syringe pump anticoagulation method . . . 8:5
Citrate – Calcium, Prismaflex Syringe Pump anticoagulation method . . . 8:6
TPE Settings . . . 8:6
Pressure sensor range, accuracy and alarm limits . . . 8:6
Access . . . 8:6
Return . . . 8:7
Filter . . . 8:7
Effluent . . . 8:9
Patient safety . . . 8:9
Air Bubble Detector . . . 8:9
Blood Leak Detector . . . 8:9
Alarm signals . . . 8:10
Audible . . . 8:10
Sound pressure levels . . . 8:10
Characteristics . . . 8:10
Visual . . . 8:10
Physical Data . . . 8:11
Weight, dimensions, etc. . . . 8:11
Scales Characteristics . . . 8:11
Scale Weight Range . . . 8:11
Scale accuracy: . . . 8:11
Power . . . 8:11
Line power . . . 8:11
Battery backup . . . 8:12
External communication . . . 8:12
Environmental data . . . 8:13
Operation . . . 8:13
Transportation and Storage . . . 8:13
Noise level . . . 8:13
Vibration levels . . . 8:14
Fluid spillage . . . 8:14
Cleanability . . . 8:14
Electromagnetic Emissions and Immunity . . . 8:14
Electrical Safety . . . 8:19
AC Leakage Current . . . 8:19
Defibrillation-proof Applied Part . . . 8:19

Radio Frequency Interference 8:19
Electromagnetic Compatibility 8:19
Potential Equalization 8:20
Continuous Operation 8:20
Conformity to International Rules 8:21
Medical Device Classification 8:22
Prismaflex® Disposable Sets 8:23
CRRT Disposable Sets 8:24
Low flow sets 8:24
Priming parameters and Blood flow rates 8:24
Patient fluid removal and Patient fluid loss/gain limit 8:24
Solution flow rates 8:25
Return Blood and Recirculation flow rates 8:25
High flow sets 8:26
Priming parameters and Blood flow rates 8:26
Patient fluid removal and Patient fluid loss/gain limit 8:26
Solution flow rates 8:27
Return Blood and Recirculation flow rates 8:27
TPE Disposable Sets 8:28
Low flow sets 8:28
Priming parameters and Blood flow rates 8:28
Return Blood and Recirculation flow rates 8:28
High flow sets 8:29
Priming parameters and Blood flow rates 8:29
Return Blood and Recirculation flow rates 8:29
HP Kits 8:30
Priming parameters and Blood flow rates 8:30
Return Blood and Recirculation flow rates 8:30

Performance

Flow Rates and Accuracy

Flow rate ranges and increment depend on the Prismaflex therapy/set combination selected by the operator. Details are listed in tables after section “Prismaflex® Disposable Sets” on page 8:23.

Blood Flow Rate

Range	10 to 450 ml/min
Increment	2 to 10 ml/min
Accuracy	±10 % of user-set rate (at nominal blood flow of 450 ml/min or the highest achievable disposable blood flow, having 37 ºC, at an access pressure of -200 mmHg and without any PBP flow).
Return Blood Flow Rate	6 to 100 ml/min When *START RETURN* softkey is pressed
Recirculation Flow Rate	20 to 100 ml/min

Automatic Blood Return Volume

Range	50 to 150% of the disposable set volume (rounded to closest 5 ml in End mode)
Increment	5% (5 ml in End mode)
Accuracy	±15%

Replacement Solution/Fluid Flow Rate

CVVH; CVVHDF	
Range	0 to 8000 ml/h
Increment	20 to 50 ml/h
CVVH	
Predilution percentage	0 to 100%
Increment	5%
CVVHDF	
Predilution percentage	0 (postdilution) or 100% (predilution)
TPE	
Range	0 to 5000 ml/h
Increment	10 ml/h
Accuracy	± 30 ml/h

Dialysate Flow Rate

CVVHD; CVVHDF	
Range	0 to 8000 ml/h
Increment	50 ml/h
Accuracy	± 30 ml/h

PBP Solution Rate

CRRT	
Range	0 to 4000 ml/h
TPE; HP	
Range	0 to 1000 ml/h Note: Total PBP Volume is 2000 ml/treatment for TPE and HP.
Increment	30 ml/h < Q_{pbp} < 100 ml/h: 2 ml/h 100 ml/h < Q_{pbp} < 200 ml/h: 5 ml/h 200 ml/h < Q_{pbp} < 1500 ml/h: 10 ml/h Q_{pbp} > 1500 ml/h: 50 ml/h Q_{pbp} = PBP Solution Flow Rate
Accuracy	± 30 ml/h

Patient Fluid Removal Performance / Patient Plasma Loss Performance

CRRT	
Range	0 to 2000 ml/h
Increment	5 to 10 ml/h
TPE	
Range	0 to 1000 ml/h
Increment	10 ml/h
Accuracy	±30 ml/h ±70 ml/3 hr ±300 ml/24 hr Scales calibrated at ambient temperature at which they will be used. Ambient temperature change less than ±3 °C (5.4 °F) during treatment.

Effluent Flow Rate

Range	0 to 10,000 ml/h Depending on the therapy selected.

Syringe Settings

Systemic, Prismaflex syringe pump anticoagulation method

Syringe Continuous Delivery Rate

Range	User controllable; 0, or 0.5 to 5.0 ml/h (20 ml syringe) 0, or 0.5 to 10.0 ml/h (30 ml syringe) 0, or 2.0 to 20.0 ml/h (50 ml syringe)
Increment	0.1 ml/h
Accuracy	±15 % < 2 ml/h, ±5 % ≥ 2 ml/h (20 ml syringe) ±10 % < 2 ml/h, ±5 % ≥ 2 ml/h (30 ml syringe) ±10 % < 3 ml/h, ±5 % ≥ 3 ml/h (50 ml syringe) Pressure between 0 and +600 mmHg. Use of approved syringes

Syringe Bolus Delivery Volume

Range	User controllable; 0, or 0.5 to 5.0 ml (20 ml syringe) 0, or 1.0 to 5.0 ml (30 ml syringe) 0, or 2.0 to 9.9 ml (50 ml syringe) 0, or 0.5 to 5.0 ml (all syringe sizes, recirculation mode)
Increment	0.1 ml
Accuracy	±15 % < 2 ml, ±5 % ≥ 2 ml (20 ml syringe) ±10 % < 2 ml, ±5 % ≥ 2 ml (30 ml syringe) ±10 % < 3 ml, ±5 % ≥ 3 ml (50 ml syringe)

Syringe Bolus Delivery Interval

Range	User controllable; Once every 1 to 24 hours Note: Immediate option also available in Run mode and Recirculation mode.
Increment	1 hour
Syringe Bolus Delivery Rate	1 ml/≤20 sec Use of approved syringes

Citrate – Calcium, Prismaflex Syringe Pump anticoagulation method

Syringe continuous delivery rate

Range	0, or 2.0 to 100 ml/h
Increment	Not applicable
Accuracy	7%

TPE Settings

Patient Hematocrit

Range	10 to 60%
Increment	1%
Default	30%

Total Replacement Volume

Range	0 to 10,000 ml
Increment	100 ml
Default	3000 ml

Replacement Container Volume

Range	0 to 5,000 ml
Increment	10 ml

Pressure sensor range, accuracy and alarm limits

Access

Operating Range	–250 to +450 mmHg
Accuracy	±15 mmHg
"Access Extremely Negative" Warning Limit	Warning alarm occurs Pressure in access pod equals warning limit.
	User controllable: –10 to –250 mmHg
Default:	–250 mmHg 150 mmHg below operating point
Increment:	5 mmHg
"Access Extremely Positive" Warning Limit	Warning alarm occurs Pressure in access pod equals warning limit.
	User controllable: +10 to +450 mmHg
Default:	+300 mmHg
Increment:	5 mmHg

"Check Access" Advisory Limit	Advisory alarm occurs When running with an operating point below –10 mmHg, this alarm occurs if access pressure is 50 mmHg or 70 mmHg (if blood flow>200 ml/min) above or below its operating point, or if the pressure rises above 0 mmHg. When running with an operating point in the range between –10 mmHg and +20 mmHg, this alarm occurs if the access pressure is 50 mmHg or 70 mmHg (if blood flow>200 ml/min) below its operating point, or if the access pressure is 10 mmHg above its operating point. When running with an operating point above +20 mmHg, this alarm occurs if the access pressure drops below +10 mmHg.

Return

Operating Range	–50 to +350 mmHg
Accuracy	±5 mmHg
"Return Extremely Positive" Warning Limit	Warning alarm occurs User controllable; +15 to +350 mmHg Default: +350 mmHg Increment: 5 mmHg Pressure in return deaeration chamber equals warning limit.
"Check Return" Advisory Limit	Advisory alarm occurs This alarm occurs if return pressure is 50 mmHg (or 70 mmHg if blood flow >200 ml/min) above its operating point.
"Return Pressure Dropping" Warning Limit	Warning alarm occurs Pressure in the return deaeration chamber is 50 mmHg (or 70 mmHg if blood flow>200 ml/min) more negative than the established operating point.
"Return Disconnection" Warning Limit	Warning alarm occurs Pressure in the return deaeration chamber is lower than +10 mmHg and the established operating point is higher than +10 mmHg.

Filter

Operating Range	–50 to +450 mmHg
Accuracy	±15 mmHg

"Set Disconnection" Warning Limit	Warning alarm occurs Pressure in filter pod (immediately before the filter) is lower than +10 mmHg.
"Filter Extremely Positive" Warning Limit	Warning alarm occurs Pressure in filter pod (immediately before the filter) is ≥450 mmHg.
"Filter Is Clotting" Advisory Limits a) Filter pressure drop b) TMP increase	Advisory alarm occurs One or both limits are reached. (CRRT) a) User controllable; +10 to +100 mmHg greater than initial filter pressure drop Default: +100 mmHg Increment: 10 mmHg b) Service controllable; +50 to +100 mmHg greater than initial TMP Default: +100 mmHg Increment: 5 mmHg
"Plasmafilter is Clotting" Advisory Limit	Advisory alarm occurs User controllable; Filter pressure drop is +10 to +60 mmHg greater than initial filter pressure drop Default: +60 mmHg Increment: 10 mmHg Limit is reached (TPE)
"HP Cartridge is Clotting" Advisory Limit	Advisory alarm occurs User controllable; Filter pressure drop is +10 to +30 mmHg (or one third of Max Pressure Drop for user defined HP cartridges) greater than initial filter pressure drop Default: +30 mmHg (or one third of Max Pressure Drop for user defined HP cartridges) Increment: 10 mmHg Limit is reached (HP)
"Filter Clotted" Warning Limit	Warning alarm occurs Filter pressure drop is ≥ limit value fixed for the filter in use, or both the "Filter is Clotting" Advisory and the "TMP Excessive" Caution limits are reached. (CRRT)
"Plasmafilter Clotted" Warning Limit	Warning alarm occurs Filter pressure drop is ≥ limit value fixed for the plasmafilter in use, or both the "Plasmafilter is Clotting" Advisory and the "TMPa Excessive" Caution limits are reached. (TPE)
"HP Cartridge Clotted" Warning Limit	Warning alarm occurs Filter pressure drop is ≥ limit value fixed for the HP cartridge in use.

"TMP Too High" Advisory Limit	Advisory alarm occurs User controllable; +70 to +350 mmHg Default: +350 mmHg Increment: 10 mmHg TMP equals user-set limit. (CRRT)
"TMPa Too High" Advisory Limit	Advisory alarm occurs User controllable; 0 to +100 mmHg Default: +100 mmHg Increment: 10 mmHg TMPa equals user-set limit. (TPE)
"TMP Excessive" Caution Limit	Caution alarm occurs TMP > limit value fixed for the filter in use (CRRT)
"TMPa Excessive" Caution Limit	Caution alarm occurs TMPa greater than a value automatically calculated by the machine depending on the blood flow rate and the plasmafilter in use. (TPE)

Effluent

Operating Range	–350 to +400 mmHg (CRRT) –350 to +400 mmHg (TPE)
Accuracy	±15 mmHg

Patient safety

Air Bubble Detector

Macro air/foam detection	Warning alarm occurs The transducer receives one voltage decrease of nominal signal level, which corresponds to detecting a single bubble/foam of approximately 20 µl. Foam sensitivity was tested using bovine blood. Air was injected into the pre-filter blood line at a rate of 1 ml/ min creating foam in the post-filter blood circuit.

Blood Leak Detector

Minimum blood leak detection	Warning alarm occurs within 20 seconds of detection. Leak ≥0.35 ml/min at 0.25 Hct, for effluent flow rate below 5500 ml/h Leak ≥0.50 ml/min at 0.32 Hct, at highest effluent flow rate.

Alarm signals

The audible and visual alarm indicators meet IEC 60601-2-16.

Audible

Sound pressure levels

Default	High volume, high pitch
Malfunction alarms	76 dB(A)
Warning alarms	67 dB(A)
Caution alarms	67 dB(A)
Advisory alarms	66 dB(A)

Characteristics

Can be silenced for 2 minutes, after which audible resumes if alarm condition has not been remedied.

Fast beep	Warning and Malfunction alarms
Moderate beep	Caution alarms
Slow beep	Advisory alarms

Unable to silence

Continuous for at least 2 minutes	Power loss

Visual

Red flashing	Warning and Malfunction alarms
Yellow flashing	Caution alarms
Yellow constantly lit	Advisory alarms

Physical Data

Weight, dimensions, etc.

Weight:	Approximately 78 kg (172 lb) Without fluid bags and Prismaflex disposable set
Height:	Approximately 163 cm (64 in)
Width:	Approximately 49 cm (19 in)
Base:	Approximately 60 cm × 63 cm (24 in × 25 in)

Scales Characteristics

Scale Weight Range

Weight range for each scale includes the scale components (bar tray, carrying bars).

Dialysate:	0 to 11 Kg
Replacement:	0 to 11 Kg
PBP:	0 to 11 Kg
Effluent:	0 to 11 Kg

Scale accuracy:

≤7 g error for a mass from 0 to 5200 g and,
≤14 g error for a mass from 5201 g to 11000 g.

Power

Line power

Line Voltage:	100 – 240 VAC
Line Current:	5 – 2.5 A (5 A maximum RMS at 100 VAC, 2.5 A maximum RMS at 240 VAC)
Frequency:	50/60 Hz
Power:	500 – 600 W
Average Energy Consumption:	<150 W (CVVHDF treatment)

Battery backup

Memory Backup	12 V / 1.2 Ah
Battery Backup	24 V / 2.9 Ah

The Prismaflex system will operate on battery backup for at least 10 minutes with healthy, fully charged batteries.

External communication

Remote Alarm	Max voltage: 24 VAC Max Current: 1 A AMP CPC (Circular Plastic Connector), 4 pin, female connector
RS232	DB9–type, female connector
Ethernet	10base-T compatible 8 pin RJ45 female connector
Technical data card	PCMCIA compatible memory card

Environmental data

Operation

Ambient Operating Temperature:	16 °C to 38 °C (60 °F to 100 °F)
Ambient Operating Humidity (for control units with serial number up to PA5409):	15% to 65% (Non-condensing)
Ambient Operating Humidity (for control units with serial number from PA5410 and on):	**Lower ambient operating humidity limit:** 15% (Non-condensing) in the temperature interval 16 °C to 38 °C. **Upper ambient operating humidity limit:** 85% (Non-condensing) in the temperature interval 16 °C to 28 °C. In the temperature interval 28 ºC to 38 ºC the upper limit is reduced by 2% per degree and at maximum ambient temperature (38 ºC) the maximum operating relative humidity is consequently 65% (Non-condensing).
Ambient Operating Air Pressure:	70 to 106 kPa (525 to 795 mmHg)

Transportation and Storage

Transport and Storage Temperature:	–18 °C to +54 °C (0 °F to 130 °F) Prior to use, let unit rest at ambient operating temperature for 1 hour.
Transport and Storage Humidity:	10% to 95% (Non-condensing)
Transport and Storage Air Pressure:	50 to 106 kPa (375 to 795 mmHg)

Noise level

Noise level	< 65 dB(A) over a 24 h period, measured at a distance of 0.5 m from the Prismaflex control unit, during normal operation and without any alarm condition.

Vibration levels

Vibrations during operation	Acceleration Spectral Density (ASD), isotropic, 2-200 Hz ASD $\leq 5\times10^{-8}$ g^2/Hz

Fluid spillage

Fluid Spillage:	IPX1 (Protection against vertically falling water drops) As specified in IEC 60529

Cleanability

Cleanability:	Not damaged by mild detergent; liquid soap; ethyl alcohol (90%); isopropyl alcohol (70%); sodium hypochlorite (0.1%). Pump rotors are removable.

Electromagnetic Emissions and Immunity

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The Prismaflex system is intended for use in the electromagnetic environment specified below. The customer or the user of the Prismaflex system should ensure that it is used in such an environment.</td></tr>
<tr><th>Emission Test</th><th>Compliance</th><th>Electromagnetic Environment – Guidance</th></tr>
<tr><td>RF emission CISPR 11 / EN 55011</td><td>Group 1</td><td>The Prismaflex system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission CISPR 11 / EN 55011</td><td>Class B</td><td rowspan="3">The Prismaflex system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions IEC / EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC / EN 61000-3-3</td><td>Complies</td></tr>
</table>

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The Prismaflex system is intended for use in the electromagnetic environment specified below. The customer or the user of the Prismaflex system should ensure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment – Guidance</th></tr>
<tr><td>Electrostatic discharge (ESD) IEC/EN 61000-4-2</td><td>±6 KV contact
±8 KV air</td><td>±6 KV contact
±8 KV air</td><td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td></tr>
<tr><td>Electrical fast transient / burst IEC/EN 61000-4-4</td><td>±2 KV for power supply lines
±1 KV for input/output lines</td><td>±2 KV for power supply lines
±1 KV for input/output lines</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Surge IEC/EN 61000-4-5</td><td>±1 KV differential mode
±2 KV common mode</td><td>±1 KV differential mode
±2 KV common mode</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000- 4-11</td><td><5% U_T (>95% dip in U_T) for 0.5 cycles
40% U_T (60% dip in U_T) for 5 cycles
70% U_T (30% dip in U_T for 25 cycles
<5% U_T (>95% dip in U_T) for 5 sec.</td><td><5% U_T (>95% dip in U_T) for 0.5 cycles
40% U_T(60% dip in U_T) for 5 cycles
70% U_T (30% dip in U_T) for 25 cycles
<5% U_T (>95% dip in U_T) for 5 sec.</td><td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Prismaflex system requires continued operation during power mains interruptions, it is recommended that the Prismaflex system be powered from an uninterruptable power supply or a battery.</td></tr>
</table>

Power frequency (50/ 60 Hz) magnetic field IEC / EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – Electromagnetic Immunity

The Prismaflex system is intended for use in the electromagnetic environment specified below. The customer or the user of the Prismaflex system should ensure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Prismaflex system including cables, than the recommended separation distance calculated from the equation applicable to frequency of the transmitter. Recommended separation distance
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 Vrms	d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz where "P" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[1] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Prismaflex system is used exceeds the applicable RF compliance level above, the Prismaflex system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Prismaflex system.

[2] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

<table>
<tr><th colspan="4">Recommended separation distances between portable and mobile RF communications equipment and the Prismaflex system</th></tr>
<tr><td colspan="4">The Prismaflex system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Prismaflex system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Prismaflex system as recommended below, according to the maximum output power of the communications equipment.</td></tr>
<tr><td rowspan="2">Rated maximum output power of transmitter (W)</td><td colspan="3">Separation distances according to frequency of transmitter (m)</td></tr>
<tr><td>150 KHz to 80 MHz
d = 1.2 √P</td><td>80 KHz to 800 MHz
d = 1.2 √P</td><td>800 KHz to 2.5 GHz
d = 2.3 √P</td></tr>
<tr><td>0.01</td><td>0.12</td><td>0.12</td><td>0.23</td></tr>
<tr><td>0.1</td><td>0.38</td><td>0.38</td><td>0.73</td></tr>
<tr><td>1</td><td>1.2</td><td>1.2</td><td>2.3</td></tr>
<tr><td>10</td><td>3.8</td><td>3.8</td><td>7.3</td></tr>
<tr><td>100</td><td>12</td><td>12</td><td>23</td></tr>
<tr><td colspan="4">For transmitters rated at maximum output power not listed above, the recommended separation distance d in meter (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

Electrical Safety

CAUTION

! Devices connected to the RS232 serial communication port or the Ethernet port must comply with IEC 60950. Connected cables must have a Kitagawa RFC-10 ferrite or equivalent to fulfill EMC requirements.

CAUTION

Note! To be sure of the machine's classification see type label found at the back of the Prismaflex control unit.

Classification:	Mobile, Class I, applied part is Type CF, defibrillation proof per IEC 60601-1
	Mobile, Class I, applied part is Type BF, defibrillation proof per IEC 60601-1
	Mobile, Class I, applied part is Type B, per IEC 60601-1 when using the Prismaflex system in combination with the MARS system.

AC Leakage Current

	Protective ground open
300 µA maximum rms	100/115 VAC, 50/60 Hz
500 µA maximum rms	220/240 VAC, 50/60 Hz

Defibrillation-proof Applied Part

Applied part is Type CF, defibrillationproof per IEC 60601-1

Applied part is Type BF, defibrillationproof per IEC 60601-1

Defibrillator equipment meets requirements of IEC 60601-2-4

Radio Frequency Interference

Meets European Standard EN 55011, limit B
Meets IEC 60601-1-2

Electromagnetic Compatibility

Meets IEC 60601-1-2

Potential Equalization

Meets IEC 60601-1

The Prismaflex control unit has a connection for a Potential Equalization Conductor.
See Rear Panel Components on page 3:14.

Continuous Operation

The Prismaflex system is intended for continuous operation.

Conformity to International Rules

IEC 60601-1:1988	Medical electrical equipment - Part 1: General requirements for safety; incl. A1:1991, A2:1995
IEC 60601-1-1:2000	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2:2001	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-4:2000	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
IEC 60601-2-16:1998	Medical Electrical Equipment - Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment
IEC 60601-2-24:1998	Medical Electrical Equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers
CAN/CSA No.601.1-M90 incl. S1-94 (R1999)	
CAN/CSA No. 601.1B-90 (R2002)	Medical Electrical Equipment - Part 1: General requirements for safety
UL 60601-1	Medical electrical equipment - Part 1: General requirements for safety

Medical Device Classification

Classification, EU	Class II b per COUNCIL DIRECTIVE 93/ 42/EEC
Classification, USA	Class II per FDA 21 CFR 876
Classification, Canada	Class III per SOR/98-282
Classification, Australia	Class II b per Therapeutic Goods Act 1989, Bill 2002

Prismaflex® Disposable Sets

Minimum blood flow range allowed by the monitor is 10 ml/min during Run mode for all sets and therapies. Reported low blood flow range limit refers to the minimum blood flow rate recommended for each set.

Maximum allowed flow rate values reported in this chapter are absolute maximum possible settings for each individual flow. Available maximum flow rate will be lowered in some therapy modes (i.e. pre- or post-replacement infusion, SCUF) and with respect to the current value of the other flow or anticoagulation settings.

CRRT Disposable Sets

Low flow sets

Priming parameters and Blood flow rates

Set	Number of priming cycles	Total priming volume (ml)	Blood flow range (ml/min)	Blood flow increment (ml/min)	Blood volume (ml)
M60	1	1000	50 to 180	5	93
ST60	1	1000	50 to 180	5	93
HF20	1	500	20 to 100	2	58

Patient fluid removal and Patient fluid loss/gain limit

Set	Unintended Fluid Loss or Gain limit (ml/3 h)	Patient fluid removal range (ml/h)	Patient fluid removal increment (ml/h)
M60	60 to 200	0 to 2000	5
ST60	60 to 200	0 to 2000	5
HF20	60 to 150	0 to 500	5

Solution flow rates

Set	Replacement flow range predilution (ml/h)	Replacement flow range postdilution (ml/h)	Replacement flow increment (ml/h)	Dialysate flow range (ml/h)	PBP flow range (ml/h)
M60	0 to 4000	0 to 3000	50	0 to 4000	0 to 2000
ST60	0 to 4000	0 to 3000	50	0 to 4000	0 to 2000
HF20	0 to 2500	0 to 2000	20	0 to 2500	0 to 1000

Return Blood and Recirculation flow rates

Set	Return Blood flow range (ml/min)	Default set value for Return Blood (ml/min)	Return Blood increment (ml/min)	Recirculation flow rate range (ml/min)	Recirculation flow rate increment (ml/min)
M60	10 to 100	40	5	30 to 100	5
ST60	10 to 100	40	5	30 to 100	5
HF20	6 to 50	20	2	20 to 50	2

High flow sets

Priming parameters and Blood flow rates

Set	Number of priming cycles	Total priming volume (ml)	Blood flow range (ml/min)	Blood flow increment (ml/min)	Blood volume (ml)
M100	1	1000	80 to 400	10	152
ST100	1	1000	80 to 400	10	152
M150	2	2000	100 to 450	10	189
ST150	2	2000	100 to 450	10	189
HF1000	1	1000	80 to 400	10	165
HF1400	2	2000	100 to 450	10	186
oXiris	2	2000	100 to 450	10	189
septeX	1	1000	80 to 400	10	164
X-MARS*	1	2000	130 to 450	10	279

*The X-MARS kit on the Prismaflex control unit requires one single priming cycle. Full priming of the X-MARS kit requires further priming cycles from the MARS monitor. Refer to MARS® Liver Support Therapy Operating Instructions and follow instructions on the Prismaflex screen.

Patient fluid removal and Patient fluid loss/gain limit

Set	Unintended Fluid Loss or Gain limit (ml/3 h)	Patient fluid removal range (ml/h)	Patient fluid removal increment (ml/h)
M100	100 to 400	0 to 2000	10
ST100	100 to 400	0 to 2000	10
M150	100 to 400	0 to 2000	10
ST150	100 to 400	0 to 2000	10
HF1000	100 to 400	0 to 2000	10
HF1400	100 to 400	0 to 2000	10
oXiris	100 to 400	0 to 2000	10
septeX	100 to 400	0 to 1000	10
X-MARS	100 to 400	0 to 1000	10

Solution flow rates

Set	Replacement flow range predilution (ml/h)	Replacement flow range postdilution (ml/h)	Replacement flow increment (ml/h)	Dialysate flow range (ml/h)	PBP flow range (ml/h)
M100	0 to 8000	0 to 6000	50	0 to 8000	0 to 4000
ST100	0 to 8000	0 to 6000	50	0 to 8000	0 to 4000
M150	0 to 8000	0 to 8000	50	0 to 8000	0 to 4000
ST150	0 to 8000	0 to 8000	50	0 to 8000	0 to 4000
HF1000	0 to 8000	0 to 8000	50	0 to 8000	0 to 4000
HF1400	0 to 8000	0 to 8000	50	0 to 8000	0 to 4000
oXiris	0 to 8000	0 to 8000	50	0 to 8000	0 to 4000
septeX	0	0 to 500	50	0 to 8000	0 to 500
X-MARS	0 to 4000	0 to 4000	50	0 to 8000	0 to 4000

Return Blood and Recirculation flow rates

Set	Return Blood flow range (ml/min)	Default set value for Return Blood (ml/min)	Return Blood increment (ml/min)	Recirculation flow rate range (ml/min)	Recirculation flow rate increment (ml/min)
M100	10 to 100	70	5	50 to 100	5
ST100	10 to 100	70	5	50 to 100	5
M150	10 to 100	70	5	50 to 100	5
ST150	10 to 100	70	5	50 to 100	5
HF1000	10 to 100	70	5	50 to 100	5
HF1400	10 to 100	70	5	50 to 100	5
oXiris	10 to 100	70	5	50 to 100	5
septeX	10 to 100	70	5	50 to 100	5
X-MARS	10 to 100	70	5	50 to 100	5

TPE Disposable Sets

Low flow sets

Priming parameters and Blood flow rates

Set	**Number of priming cycles**	**Total priming volume (ml)**	**Blood flow range (ml/min)**	**Blood flow increment (ml/min)**	**Blood volume (ml)**
TPE1000	2	2000	50 to 180	5	71
TPE20	1	1000	50 to 180	5	65

Return Blood and Recirculation flow rates

Set	**Return Blood flow range (ml/min)**	**Default set value for Return Blood (ml/min)**	**Return Blood increment (ml/min)**	**Recircula-tion flow rate range (ml/min)**	**Recircula-tion flow rate in-crement (ml/min)**
TPE1000	10 to 100	40	5	30-100	5
TPE20	10 to 100	40	5	30-100	5

High flow sets

Priming parameters and Blood flow rates

Set	Number of priming cycles	Total priming volume (ml)	Blood flow range (ml/min)	Blood flow increment (ml/min)	Blood volume (ml)
TPE2000	3	3000	100 to 250/400[3]	5	125
TPE60	1	1000	100 to 400	5	146

Return Blood and Recirculation flow rates

Set	Return Blood flow range (ml/min)	Default set value for Return Blood (ml/min)	Return Blood increment (ml/min)	Recircula-tion flow rate range (ml/min)	Recircula-tion flow rate in-crement (ml/min)
TPE2000	10 to 100	70	5	50 to 100	5
TPE60	10 to 100	70	5	50 to 100	5

[3] Depending on machine default set up

HP Kits

Priming parameters and Blood flow rates

Set	Number of priming cycles	Total priming volume (ml)	Blood flow range (ml/min)	Blood flow increment (ml/min)	Blood volume (ml)
Adsorba 150	3	2500	50 to 250	10	247
Adsorba 300	3	2500	100 to 350	10	367
HP-X	User defined[4]	1000 to 15000	50 to 450	10	108[5]

Return Blood and Recirculation flow rates

Set	Return Blood flow range (ml/min)	Default set value for Return Blood (ml/min)	Return Blood increment (ml/min)	Recircula-tion flow rate range (ml/min)	Recircula-tion flow rate in-crement (ml/min)
Adsorba 150	10 to 100	70	5	30 to 100	5
Adsorba 300	10 to 100	70	5	50 to 100	5
HP-X	10 to 100	50	5	50 to 100	5

[4] Defined by dividing priming volume and bag volume for user defined cartridge in Custom mode.

[5] Only for the line set. Blood volume for user defined cartridge shall be added for total blood volume.

Chapter 9

Equations

Blood pump flow rate 9:2
Filter pressure drop 9:2
Effluent flow rate 9:2
Transmembrane pressure 9:3
Total predilution 9:3
CRRT prescription indicators 9:3
Filtration Fraction 9:4
Doses 9:4
Patient fluid removed 9:5
Access transmembrane pressure 9:5
Software Calculations of Target Patient Plasma Loss 9:5
Formulas used in TPE 9:6
Patient plasma loss 9:6
PBP flow rate 9:7
Syringe flow rate 9:7

Blood pump flow rate

The PBP solution is added to the access line immediately after the patient's blood enters from the access site, and before the access line reaches the blood pump. Because of this, the amount of blood actually pumped with each revolution of the blood pump is reduced. To maintain the set blood flow, the Prismaflex software increases the blood pump flow:

$$Q_{BP} = Qb + Q_{pbp}$$

Where $\mathbf{Q_{BP}}$ is blood pump flow (ml/min), **Qb** is set blood flow (ml/min) and $\mathbf{Q_{pbp}}$ is set PBP flow (ml/min).

Filter pressure drop

Filter pressure drop is a calculated value used to determine pressure conditions in the blood compartment of the filter. Filter pressure drop is calculated by Prismaflex software as follows:

$$\Delta P_{fil} = P_{fil} - P_{ret}$$

Where $\mathbf{\Delta P_{fil}}$ is Filter pressure drop (mmHg), $\mathbf{P_{fil}}$ is Filter pod pressure (mmHg) and $\mathbf{P_{ret}}$ is Return sensor pressure (mmHg)

Filter pressure and Return pressure readings are automatically corrected for hydrostatic pressure biases (–25 mmHg).

Effluent flow rate

The formula which governs the effluent pump rate for CRRT:

$$Q_{eff} = Q_{pfr} + Q_{pbp} + Q_{rep} + Q_{dial} + Q_{syr}$$

Where $\mathbf{Q_{eff}}$ is Effluent rate (ml/h), $\mathbf{Q_{pfr}}$ is Patient fluid removal rate (ml/h), $\mathbf{Q_{pbp}}$ is PBP flow rate (ml/h), $\mathbf{Q_{rep}}$ is Replacement solution rate (ml/h), $\mathbf{Q_{dial}}$ is Dialysate solution rate (ml/h) and $\mathbf{Q_{syr}}$ is Syringe flow rate (ml/h)

The Prismaflex software automatically calculates the effluent flow rate needed to achieve the patient plasma loss rate. Any replacement solution infused by the Prismaflex control unit is automatically accounted for, as shown below:

$$Q_{eff} = Q_{ppl} + Q_{rep}$$

Where $\mathbf{Q_{eff}}$ is Effluent rate (ml/h), $\mathbf{Q_{ppl}}$ is Patient plasma loss rate (ml/h) and $\mathbf{Q_{rep}}$ is Replacement fluid rate (ml/h)

Transmembrane pressure

Transmembrane pressure is the pressure exerted on the filter membrane during operation of the Prismaflex system. It reflects the pressure difference between the blood and fluid compartments of the filter.

The TMP is calculated by Prismaflex software as follows:

$$TMP = [(P_{fil} + P_{ret}) / 2] - P_{eff}$$

Where **TMP** is Transmembrane pressure (mmHg), $\mathbf{P_{fil}}$ is Filter pressure (mmHg), $\mathbf{P_{ret}}$ is Return pressure (mmHg) and $\mathbf{P_{eff}}$ is Effluent pressure (mmHg)

Filter pressure and effluent pressure readings are automatically corrected by software for hydrostatic pressure biases to compute and display TMP data (–18 mmHg correction).

Total predilution

The Prismaflex software calculates the total predilution value, which is the ratio of prefilter blood dilution to the total blood dilution. Total predilution is calculated according to the formula below:

$$PRE\%_{tot} = (Q_{pbp} + Q_{rep(pre)}) / (Q_{pbp} + Q_{rep})$$

Where $\mathbf{PRE\%_{tot}}$ is Total predilution (%), $\mathbf{Q_{pbp}}$ is PBP flow rate (ml/h), $\mathbf{Q_{rep}}_{pre}$ is Pre-filter replacement flow rate (ml/h), $\mathbf{Q_{rep}}$ is Replacement flow rate (ml/h)

CRRT prescription indicators

Three prescription indicators are computed as a function of flow rate settings, patient body weight and hematocrit value:

- Filtration Fraction represents the level of internal filtration over the filter membrane within the disposable set.
- Effluent Dose represents the effluent flow rate normalized to patient body weight.
- Ultrafiltration Dose represents the fluid amounts contributed by PBP, replacement and patient fluid removal rates, normalized to patient body weight.

Following abbreviations are used in the equations for each prescription indicator:

Abbreviation	Explanation	Unit
$D_{CRRT\text{-}eff}$	Effluent dose	ml/kg/h
Q_{eff}	Effluent flow rate	ml/h
BW	Patient body weight	kg
$D_{CRRT\text{-}UFR}$	Ultrafiltration dose	ml/kg/h
Q_{plasma}	Plasma water flow rate (at patient access)	ml/h
Q_{pre}	Pre-infusion flow rate	ml/h
Q_{UFR}	Ultrafiltration rate	ml/h
Q_{pbp}	PBP flow rate	ml/h
Q_{dial}	Dialysate flow rate	ml/h
Q_{rep}	Replacement flow rate	ml/h
Q_{pfr}	Patient fluid removal flow rate	ml/h
QP_{pfl}	Prescribed patient fluid loss	ml/h
Qb	Blood flow rate	ml/h
PRE%	Predilution	%
Hct	Hematocrit (default value 30%)	%
FF	Filtration fraction	%

With

$Q_{eff} = Q_{pbp} + Q_{dial} + Q_{rep} + Q_{pfr}$

$Q_{plasma} = (1 - (Hct / 100)) \times Qb$

$Q_{pre} = Q_{pbp} + (PRE\% / 100) \times Q_{rep}$

$Q_{UFR} = Q_{pbp} + Q_{rep} + Q_{pfr}$

Filtration Fraction

Filtration fraction (FF) is calculated according to the formula below:

$FF = 100 \times (Q_{UFR}) / (Q_{plasma} \times 0.95 + Q_{pre})$

Doses

Effluent dose ($D_{CRRT\text{-}eff}$) and the Ultrafiltration dose ($D_{CRRT\text{-}UFR}$) are calculated according to the formula below:

$D_{CRRT\text{-}eff} = Q_{eff} / BW$

$D_{CRRT\text{-}UFR} = [Q_{plasma} / (Q_{plasma} + Q_{pre})] \times (Q_{UFR} / BW)$

Patient fluid removed

The four precision scales mounted on the bottom of the Prismaflex control unit support the PBP, replacement solution, dialysate, and effluent bags and constantly measure the weight of the bags. The change in combined weight of the fluid bags in use indicates how much fluid has been removed from the patient by the control unit. When fluid bags are replaced, the software automatically accounts for the new bag weights. The following formula applies:

$V_{pfr} = V_{eff} – V_{pbp} – V_{dial} – V_{rep} – V_{syr}$

Where $\mathbf{V_{pfr}}$ is Patient fluid removed (ml), $\mathbf{V_{eff}}$ is Effluent bag volume (ml), $\mathbf{V_{pbp}}$ is PBP pumped (ml), $\mathbf{V_{dial}}$ is Dialysate pumped (ml), $\mathbf{V_{rep}}$ is Replacement solution pumped (ml) and $\mathbf{V_{syr}}$ is Syringe solution pumped (ml).

Access transmembrane pressure

Access transmembrane pressure is the pressure difference between the blood and fluid compartments at the inlet side of the filter.

The TMPa is calculated by Prismaflex software as follows:

$TMPa = P_{fil} – P_{eff}$

Where **TMPa** is Access transmembrane pressure (mmHg), $\mathbf{P_{fil}}$ is Filter pressure (mmHg) and $\mathbf{P_{eff}}$ is Effluent pressure (mmHg)

Filter pressure and effluent pressure readings are automatically corrected by software for hydrostatic pressure biases to compute and display TMPa data (–30 mmHg correction).

Software Calculations of Target Patient Plasma Loss

Prismaflex software calculates a Target Patient Plasma Loss based on settings entered by the operator. This calculated value is displayed on the `Enter TPE Prescription` and `Enter Flow Settings` screens.

Software calculates the Target Patient Plasma Loss by first determining the treatment time according to the formula below.

$T = V_{rep(tot)} / Q_{rep}$

Where **T** is Treatment time (h), $\mathbf{V_{rep(tot)}}$ is Volume to replace (Total Replacement Volume (ml)) and $\mathbf{Q_{rep}}$ is Replacement fluid rate (ml/h)

Target Patient Plasma Loss is then calculated as follows:

$V_{ppl(tgt)} = Q_{ppl} \times T$

Where $\mathbf{V_{ppl(tgt)}}$ is Target patient plasma loss (ml), $\mathbf{Q_{ppl}}$ is Patient plasma loss rate (ml/h) and **T** is Treatment time (h)

Formulas used in TPE

Below is a summary of the formulas used by Prismaflex software in managing TPE. Software calculations are based on the operator-set TPE Prescription and flow rate values. The results of software calculations are displayed on the `Enter TPE Prescription` and/or `Flow Rates` screens.

$V_{plasma} = (100 - Hct) \times 0.7 \times BW$

where **Vplasma** is Patient plasma volume (ml), **Hct** is Hematocrit (%), **BW** is Patient body weight (kg)

$R_{exch} = V_{rep(tot)} / V_{plasma}$

where $\mathbf{R_{exch}}$ is Plasma volume exchange (dimensionless), $\mathbf{V_{rep(tot)}}$ is Total Replacement Volume (ml) and **Vplasma** is Patient plasma volume (ml)

$Hct_{post} = [(Qb / (Qb - Q_{eff})] \times Hct$

where $\mathbf{Hct_{post}}$ is Post-filter Hematocrit (%), **Qb** is Operator set blood flow rate (ml/h), **Hct** is Hematocrit (%) and $\mathbf{Q_{eff}}$ is Effluent flow rate (ml/h)

$FF = 100 \times (Q_{rep} + Q_{ppl}) / (Q_{plasma} \times 0.95 + Q_{pbp})$

$Q_{plasma} = (1 - (Hct / 100)) \times Qb$

where **FF** is Filter fraction (%), $\mathbf{Q_{ppl}}$ is Patient plasma loss rate (ml/h), $\mathbf{Q_{rep}}$ is Replacement flow rate (ml/h), **Qb** is Operator set blood flow rate (ml/h), **Hct** is Hematocrit (%), Q_{pbp} is PBP flow rate (ml/h) and $\mathbf{Q_{plasma}}$ is plasma flow rate (ml/h)

$V_{eff(tgt)} = Q_{eff} \times T$

where $\mathbf{V_{eff(tgt)}}$ is Target effluent (ml), $\mathbf{Q_{eff}}$ is Effluent rate (ml/h) and **T** is Treatment time (h)

$V_{ppl(tgt)} = Q_{ppl} \times T$

where $\mathbf{V_{ppl(tgt)}}$ is Target patient plasma loss (ml), $\mathbf{Q_{ppl}}$ is Patient plasma loss rate (ml/h) and **T** is Treatment time (h)

Patient plasma loss

The replacement scale and effluent scale mounted on the bottom of the Prismaflex control unit support the replacement fluid bag/container and effluent bag and constantly measure their weights. The change in combined weight of the fluid bags/containers in use indicates how much plasma has been removed from the patient by the control unit.

When fluid bags/containers are replaced, the software automatically accounts for their new weights. The following formula applies:

$V_{ppl} = V_{eff} - V_{rep}$

Where $\mathbf{V_{ppl}}$ is Patient plasma loss (ml), $\mathbf{V_{eff}}$ is Effluent bag volume (ml) and $\mathbf{V_{rep}}$ is Replacement solution volume (ml)

PBP flow rate

In citrate anticoagulation, PBP flow rate is kept proportional to blood flow rate and computed by the software through the equation:

$Q_{pbp} = (Qb \times D_{cit}) / [Cit]$

Where $\mathbf{Q_{pbp}}$ is PBP flow rate (ml/h), **Qb** is Blood flow rate (ml/h), $\mathbf{D_{cit}}$ is Citrate dose expressed in millimole per liter of blood (mmol/l blood) and **[Cit]** is citrate concentration of the PBP solution (mmol/l).

Syringe flow rate

In “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method, the syringe flow rate is kept proportional to the estimated calcium loss rate in effluent. It is computed by the software of the Prismaflex system through the equation:

$Q_{syr} = CaComp \times J_{Ca} / [Ca] - Q_{rep} \times [Ca_{rep}] / [Ca]$

Where **CaComp** is the calcium compensation, $\mathbf{Q_{syr}}$ is syringe flow rate (ml/h), $\mathbf{J_{Ca}}$ is estmated calcium loss rate in effluent (mmol/h), **[Ca]** is calcium concentration of the syringe solution (mmol/l), Q_{rep} is the replacement flow rate (ml/h), and $[Ca_{rep}]$ is calcium concentration of the replacement solution in post-dilution (mmol/l).